IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

THE CITY OF HUNTINGTON,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01362
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	
CABELL COUNTY COMMISSION,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01665
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	

BENCH TRIAL - VOLUME 40
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JULY 28, 2021

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Proceedings recorded by mechanical stenography;
transcript produced by computer.

PROCEEDINGS had before The Honorable David A. Faber, Senior Status Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on July 28, 2021, at 9:00 a.m., as follows:

THE COURT: Good morning.

You may go forward, Ms. Mainigi, when you're ready.

MS. MAINIGI: Thank you, Your Honor.

Your Honor, the plaintiffs put on a long case, but they spent a long time on issues that were not in dispute.

Most of their witnesses talked about whether Cabell County and Huntington have experienced an opioid epidemic. But all three defendants told Your Honor from day one that we're not disputing the opioid problem.

The question, rather, is whether the defendants engaged in unreasonable conduct that caused harm in Cabell and Huntington.

And over 32 trial days, the Court heard very little about Cardinal Health's conduct. Now, not counting the McKesson and ABDC witnesses, plaintiffs called a total of 26 live witnesses. Thirteen of them, Your Honor, were fact witnesses. Ten of those witnesses testified only about the use of opioids or harms from drug addiction. None of those 10 said a word about Cardinal Health.

The only live three fact witnesses that -- the only

three live fact witnesses that talked about Cardinal Health's conduct were Mr. Rannazzisi, Michael Mone, and Jesse Kave. We will cover Mr. Rannazzisi's testimony in detail later. But he acknowledged that he doesn't know anything about Cardinal Health since 2012.

And the testimony from Mr. Mone and Mr. Kave, the two former Cardinal Health employees who testified, shows why Cardinal Health's conduct was reasonable.

Now, Your Honor, there were also 13 expert witnesses. And 10 of them also offered no opinions on Cardinal Health.

The three experts that did talk about us are the three that you see lit up below.

Jakki Mohr said we engaged in marketing. But she didn't say any of our marketing was false or misleading or improper in any way, or that we did anything wrong or caused any harm.

Dr. McCann, as you know, just calculated what was distributed into Cabell and Huntington and compared it to other places. He did not evaluate our conduct.

And then, of course, you've heard a lot about Mr. Rafalski. I'll come back to him. But, essentially, he had nothing to offer but *ipse dixit* conclusions without any meaningful review of our systems or our procedures.

Now, plaintiffs during this entire trial did not identify a single actual order that was suspicious that we

shipped to a customer in Cabell or Huntington. They gave the Court no specific evidence of our conduct to support a liability finding.

And to the extent that they focused on us at all, Your Honor, it was about the overall volume of the prescription opioid orders that we shipped. But volume does not equal wrongdoing.

The evidence was overwhelming and uncontroverted. What caused the increase in volume was the change in the standard of care. When the standard of care changed, doctors prescribed more opioids to treat pain. And the evidence shows that they wrote those prescriptions in good faith.

Mr. Rannazzisi testified that 99 percent of doctors were perfect. And that's why the DEA increased the opioid production quota year after year after year. It decided the increases were necessary to meet legitimate medical needs.

Now, Mr. Rannazzisi also told us he couldn't cut the quota arbitrarily even if he thought some people were abusing opioids because legitimate patients would be denied their medication.

But that's what the plaintiffs are saying we should have done. They're coming here and saying that we should have second-guessed the doctors and arbitrarily cut orders.

When you take Mr. Rafalski's now famous 90 percent flagging number and you marry it up with the testimony that

99 percent of doctors are perfect, those two just cannot come together, Your Honor.

Now, Ms. Kearse when she spoke yesterday, she spoke in terms of over-supply. And I think you asked her a question about that.

On that issue, Mr. Rannazzisi himself admitted that supply does not drive demand.

THE COURT: There are economists that disagree with that.

MS. MAINIGI: Excuse me, Your Honor?

THE COURT: There are economists that would disagree with that.

MS. MAINIGI: There are economists that would disagree with that. But Mr. Rannazzisi was on the ground and was increasing the quota year after year. And he testified supply does not drive demand, which I think is a critical, critical point here.

And I think as Your Honor knows from having sat through, very carefully through this trial, our view is that the prescribing drives the demand. And that demand is what drives the supply. And that determines the volume.

And as I said in the opening, Your Honor, distributors are a mirror of what's happening in healthcare. We reflect it. We don't drive it.

Now, plaintiffs did not just fail to put on evidence of

our conduct. They ignored, in our view, the question of causation.

At the end of this trial, there is no proof of a causal link between Cardinal Health's conduct and the harms in Cabell and Huntington. All we have are Mr. Rafalski's totally unsupported claims. No one has tried to tie our conduct to causing harm.

And no witness, even Mr. Rafalski, no witness has accounted for the intermediate steps in the causal chain; doctors prescribing, pharmacies dispensing, patients diverting, and users misusing. That wasn't discussed yesterday or during trial. And there's no witness that has given the Court a basis to find that we were a direct cause.

So we're left with the failure of proof on every dimension of plaintiffs' claim. None of the evidence shows Cardinal Health's conduct was unreasonable. None of it proves causation.

And on abatement, Your Honor, the relief that the plaintiffs seek, it's not abatement. It's not tethered to the actual needs of Cabell and Huntington. And it's not tied to our conduct.

And this chart, Your Honor, will serve as a roadmap for the issues that I intend to cover and the evidence that I intend to bring to your attention.

So let me start with reasonableness.

I think where we're at, Your Honor, is that everyone agrees that plaintiffs must prove that our conduct was unreasonable. So if the Court finds ultimately that our conduct was reasonable, there is no liability here.

And here are some of the key facts that go into that that are completely undisputed, Your Honor. Cardinal Health distributes only to pharmacies that are licensed by the state and federal government. And those pharmacies fill prescriptions written by doctors who are also licensed by the state and federal government.

The medications we distribute, as Your Honor knows, are approved by the FDA and they're subject to quotas set by the DEA.

Our West Virginia distribution center in Wheeling, the only distribution center that has served Cabell and Huntington, has been approved by the Board of Pharmacy and has never been the subject of a DEA action.

There is no evidence of any of our many customers in Cabell and Huntington diverting. And there's no evidence in all these days of trial of any specific order that we shipped that we should not have shipped.

So how do plaintiffs get to unreasonable? Well, as Your Honor knows, the plaintiffs started their case by saying that there was something unreasonable about all of our Suspicious Order Monitoring Systems. And we had days

and days and days of company witnesses.

But when that didn't pan out with the company witnesses, their entire case became about volume, Your Honor. They doubled down on volume and volume alone. They argued yesterday, and they argued throughout this trial, that the volume of prescription opioid orders we shipped was inherently unreasonable.

THE COURT: Is there some point at which the number would be so great it would be unreasonable in and of itself?

MS. MAINIGI: I don't think volume alone can be measured, Your Honor, because the volume has to be tethered to something. They have to provide the context for the particular volume.

I think -- Mr. Nicholas went over -- let me give you an example. Mr. Nicholas went over this yesterday and I intend to just cover it briefly today.

Dr. McCann and Ms. Keller both did different calculations. Dr. McCann did a calculation of distribution. And -- excuse me. Dr. McCann did a calculation of distributions and Ms. Keller did a calculation related to prescriptions.

And on cross-examination, Your Honor, she calculated that the amount distributed into Cabell/Huntington in some of these relevant years to the pill, to the pill matched up

with the prescriptions and the pills that were going out per the prescriptions.

So I think in this case, Your Honor, when there is a complete one-to-one match-up with the prescriptions that were written on the one hand and the distributions that went out from these three distributors on the other, that is inherently reasonable.

And Mr. Rafalski, as I'll go over, Your Honor, backed that up. He said he wasn't aware of any order that was not tied ultimately to a prescription.

And, in fact, Your Honor, this is a good time for me to put up the testimony, one piece of testimony from Dr. McCann.

Dr. McCann testified that prescriptions and distributions are two sides of the same coin. That was Dr. McCann's testimony. They're two sides of the same coin. And, so, when those two sides --

THE COURT: I'm sorry to interrupt you, but the overflow room video is not working and we need to reboot it. I'm sorry to interrupt you.

MS. MAINIGI: No rush, Your Honor. Should I wait right here?

(Pause)

THE COURT: Okay. I guess we're ready to go.

MS. MAINIGI: Okay. Thank you, Your Honor.

So two sides of the same coin for distributions and prescribing.

So if we want to understand the number of opioids that were distributed in Cabell and Huntington, the real question is why did the doctors write the number of prescriptions that they wrote.

And the Court has heard testimony from the beginning of this trial about that issue from both sides' witnesses. And I think you heard from Dr. Deer and Dr. Gilligan, for example, that from the 1990s through the early 2010s, the standard of care increasingly called for the use of opioids to treat pain. And doctors responded by doing that -- exactly that.

And Dr. Deer testified that increased prescribing was entirely reasonable based on the information available at the time.

So we've got two of the country's leading experts, Dr. Tim Deer, who is from right here in Charleston, and Dr. Chris Gilligan, who is from Harvard Medical School.

Dr. Deer was asked by West Virginia University to actually draft the state's opioid prescribing guidelines. And they both testified that the standard of care changed starting in the mid 1990s to encourage greater use of opioids. And that trend continued until the last decade. And that trend happened in West Virginia and it happened

nationally.

I'm going to put up, Your Honor, a chart that I used with Dr. Deer. This underlying chart, the blue and orange, Your Honor, you may remember is the chart that Mr. Farrell wheeled out in his opening and that he ultimately went over with Dr. McCann.

And the blue and the orange bars are distributions of oxycodone and hydrocodone in West Virginia.

And you can see that the distributions rose as the standard of care evolved to encourage greater prescribing. And then the distributions fell as the standard of care evolved to prescribe fewer opioids.

And that makes sense because the distributors' role is to ensure that medications are available for pharmacies to fill legitimate prescriptions. And that's exactly what happened. The distributions tracked the changing standard of care.

Now, let me walk through the timeline, Your Honor, the evolution of the standard of care.

Dr. Deer and Dr. Gilligan both explained that prescribing opioids for chronic pain wasn't common in the '80s and the early '90s. Opioids were mainly used after surgery or at the end of life.

In 1996 Purdue launched Oxycontin. And around that same time period, we saw the adoption of pain as the fifth

vital sign. And that meant when a patient was treated at a hospital or the V.A., they had to be asked their pain level. And then doctors had to treat them to lower or eliminate that pain.

And there were a lot of influential organizations that embraced this idea at the time. One of them was the American Pain Society which was led by a prominent Johns Hopkins physician.

Others in the community began to adopt this concept pretty broadly. And as I go through -- I'm not going to pull out -- in the interest of time, Your Honor, I'm not going to pull out documents to show you. But I handed up to the Court a binder of documents when we put Dr. Deer on. And those -- that binder contains all of the documents that are ultimately on this timeline.

So in 2000 the V.A. issued a pain as the fifth vital sign tool kit. And that instructed providers to evaluate pain and initiate interventions to relieve it if it was present at any level, any level.

And around that same time, hospitals started adopting policies to treat the under-treatment of pain.

Now, we've heard a lot about the Joint Commission and that's the body that accredits hospitals around the country.

Drs. Deer and Gilligan testified that in 2001 the Joint Commission made pain as the fifth vital sign. It made it

part of its accreditation standards. And then we know, fast forward, they ultimately got sued by the City of Huntington for that reason.

Now, this change as part of the accreditation standards required doctors to assess and address pain in every single patient they saw in a hospital. And, so, doctors responded, as you would think they would respond, by prescribing more opioids.

Mayor Williams got on the stand here at this trial and testified that, yes, the City of Huntington sued the Joint Commission because they thought pain as the fifth vital sign caused the opioid epidemic.

Now, the DEA also helped change the standard of care. In 2001 the DEA issued a joint statement with 21 health organizations, including the AMA and The American Cancer Society. And that statement promoted pain relief.

The DEA said the under-treatment of pain was a serious problem in the United States. And it went on to say that opioid medications are often the most effective way to treat pain. And they're the -- and most often, they're the only treatment option that provides significant relief to patients.

Now, while some of this stuff was happening nationally, the same type of thing was happening in West Virginia, as we know.

In 1997 -- and West Virginia was even a little bit ahead of the curve. In 1997 the State Board of Medicine put out a statement telling doctors pain was under-treated. And it told doctors not to fear discipline for treating chronic pain, chronic pain, not end of life pain, not cancer pain, but chronic pain with opioid medication even in large doses. And that "even in large doses" is a direct quote, Your Honor.

So the next year in 1998 the State Legislature of West Virginia made that statement official. And they passed something called the Intractable Pain Act. And that act did two major things.

First, it encouraged doctors to prescribe opioids more freely. And, second, it made clear that if they did, disciplinary action would be limited.

Your Honor, if you don't mind, I'll just give you a copy of the slides right now. It might be easier to read that.

THE COURT: That would be great. Thank you very much.

MS. MAINIGI: I think it's just a few pages in. I know it's a little tight on the chart.

So the Intractable Pain Act in 1998 encouraging doctors to prescribe more opioids, and then making clear that if they did, disciplinary actions would be limited. And those

two actions in '97 and '98 helped to start shifting the standard of care in West Virginia.

In 2001 the Board of Medicine in West Virginia issued a joint policy statement on pain management at the end of life. And in that policy statement, they continued to encourage the use of opioids for pain. And they actually said to doctors, "Don't shy away from prescribing opioids just because they might be misused."

In 2005 the Board of Medicine again encouraged opioid prescribing through another statement that went to doctors. And that statement said under-treating pain -- under-treating pain constituted inappropriate treatment which could expose a doctor to discipline.

So let's think about how quickly things changed.

In 1998 the Legislature felt they had to protect doctors from getting in trouble for prescribing too many opioids. But by 2005 in West Virginia, the Board of Medicine was telling doctors they could get in trouble for not prescribing enough opioids.

Now, that same year in 2005 the state AG at the time joined in. And he and other Attorneys General wrote the DEA to express their concern that there was too much focus on anti-diversion and not enough focus on the treatment of pain.

And Dr. Deer told us when he came to testify that that

AG letter was reprinted in the Board of Medicine newsletter that went to every licensed doctor in the state.

Now, West Virginia going into 2009 and 2010, West Virginia continued to promote opioids to treat pain.

So in 2009, the Legislature actually amended the Intractable Pain Act, the one that was passed in 1998. And they amended it to remove the word "intractable."

Dr. Deer testified that this made it easier for doctors to prescribe opioids for patients with less severe pain, not just intractable pain. And they were able to prescribe for less severe pain without a fear of consequence.

And in 2010 the Board of Medicine re-adopted the same joint statement on pain management that it had put out in 2001.

Now, while all of these laws and policies were changing, Dr. Deer explained to us that in the background of all of this, continuing education for doctors also increased opioid prescribing.

And I think that you've seen a few times, and I think that you have a copy of, Your Honor, this book called *Responsible Opioid Prescribing* by Dr. Fishman. And this book is important because it's, it's a key example of a book that was handed out to doctors in West Virginia by the Board of Medicine. And the book essentially urges doctors to prescribe opioids more liberally. It was sent to every

doctor in West Virginia.

And the plaintiffs' own complaint said that Dr. Fishman's book was a major reason that prescribing went up in West Virginia.

And West Virginia wasn't alone. There were a number of states that actually sent that book out to doctors. And I think Your Honor even heard during trial an example of a doctor who had to write a book report about Dr. Fishman's book as part of a disciplinary action.

And Dr. Deer told us when he was here that the Board of Medicine required doctors to watch a lecture by Dr. Fishman in order to renew their licenses.

So Dr. Deer concluded that all of these laws, education programs and policies, those resulted in the increased opioid prescribing across the state.

Now, what he also testified to was that doctors who were doing that prescribing were acting reasonably and following the standard of care. And he was asked that question and he said, "I think at the time, the vast majority of those doctors were acting within reasonable medical standards and standard of care."

And you saw from the chart, Your Honor, that as prescribing went up, distributions, of course, went up too.

So we come back to the timeline. The standard of care pendulum begins to shift around 2012 in West Virginia. And

it starts to shift in the other direction.

And in that year, in 2012, the West Virginia Legislature passed the Controlled Substances Monitoring Program and Chronic Pain Clinic Licensing Act. It's a mouthful of an act. And this act did two things also.

It required doctors to check a prescribing database to spot doctor-shopping. Now, why was that important? Because there were people that were going to multiple doctors perhaps to get the same prescription.

So doctors now actually had to take -- had to check a database that was available to them, not available to distributors, but available to them as physicians to see if anyone else, any other doctor had prescribed a controlled substance to that same patient. The act also required pain clinics to have special licenses.

Now, in the last several years in particular, the medical community, as well -- in West Virginia, as well as the rest of the country, has moved towards more conservative prescribing of opioids.

In 2016 the seminal event was that the CDC issued new guidelines that recommended quantity and dosage limits for prescribing opioids, actual limits on how much opioids one could prescribe.

So West Virginia followed. And later that year, a panel of doctors that was led by Dr. Deer issued the SEMP

guidelines. And the purpose of the SEMP guidelines was to essentially translate the CDC guidelines into practical advice for physicians in West Virginia.

Then in 2018 the -- the West Virginia Legislature took even stronger action and they passed the West Virginia Opioid Reduction Act which for the first time limited the number of pills doctors could prescribe.

And, so, you see ultimately prescriptions falling. And as prescriptions fell, distributions fell.

What was striking about the issue of standard of care, Your Honor, throughout this trial was how much of the standard of care evidence actually came from the plaintiffs' own witnesses long before we got to Dr. Gilligan and Dr. Deer in our case.

So Dr. Werthammer was a plaintiffs' witness. He's the former Chief Medical Officer at Marshall Health. And Dr. Werthammer agreed that pain as the fifth vital sign led to more liberal opioid prescribing.

Dr. Gupta, who was the Health Commissioner and Secretary of the Board of Medicine, he testified that most doctors in the state were prescribing in line with the standard of care and trying to do the right thing. And he said that prescribing opioids to treat pain was their education. It was their understanding. And it was their culture.

Dr. Corey Waller, who was the plaintiffs' very first witness who talked about molecules, he confirmed the standard of care change. And he also said pain had to be treated, and the general gestalt in the medical community was that prescription opioids were the only way to do it.

Even Dr. Katherine Keyes, plaintiffs' epidemiologist, she agreed that opioid prescribing rose from the late '90s until 2010. And she said -- I'll read this out loud.

"As I've said before, the doctor is making a determination based on their understanding of the risks and benefits of a particular opioid prescribing, which itself has changed over time. You know, certainly, the recommendations for prescribing have changed quite a lot over the last 10 years."

Now, Dr. Kevin Yingling who's local to Marshall, he testified that he also came to believe that pain was under-treated in the late 1990s. And he said doctors were urged to treat pain more aggressively. He said he and other local doctors prescribe more opioids in part because of pain as the fifth vital sign.

And one of the other things he said, as you see at the bottom, Your Honor, is distributors have never had an effect on his prescribing behavior.

Now, he also told us, Your Honor, that there's a debate in the medical community that's going on still today as to

whether opioid prescribing restrictions have now gone too far, whether they are too strict, and whether they are actually now hurting patients in real pain.

Now, Your Honor, to be clear, we do not think that Your Honor is tasked with deciding whether the standard of care for prescribing opioid medications in retrospect was right or wrong. You don't have to decide that in our view.

But what the Court has to evaluate here is whether defendants' conduct, including their shipments over time, was reasonable in light of the standard of care and its impact on prescribing.

So whether it was right or wrong, there's no dispute about the change in the standard of care. And there's no dispute that distributors played no role in that change. Not a single witness testified to that fact.

And what we know from Dr. Gilligan and others is that opioids, like all medications, have always carried risks. He testified that it was inevitable that with the prescribing of opioids comes some level of abuse and addiction, but that doctors must make the decision on how to strike that balance.

Now, I think some of this testimony got shown to you yesterday, Your Honor. And, and the plaintiffs put it out there as something that somehow supports the idea of foreseeability. But I, I think that they are missing the

point.

I think what this testimony supports is that doctors have to make the decision on a patient-by-patient basis whether the risks of opioids outweigh the benefits. And the distributors do not have the information or the medical expertise to make that decision, and they should not ever be put in the position of trying.

Distributors cannot unilaterally decide to stop shipping an FDA approved medication simply because a certain portion of the population may experience what is known as a known risk.

Now, Mr. Rannazzisi even testified and agreed that distributors have never been required to monitor prescribers or prescribing practices. He said we never required them to look at what doctors were doing, questioning a doctor's prescribing habits.

Speaking of the DEA, there's another important place where the change in the standard of care was reflected, Your Honor, and that's the DEA opioid quota.

So we put Dr. Deer's timeline back up. This shows, as I mentioned, the West Virginia distribution. I think we also showed you at some point during trial the DEA quota chart.

And if we can put that up, the point that I want to make, Your Honor, is that the quota trend line matches the

distribution trend line which, again, makes perfect sense because the DEA sets the quota every year based on legitimate medical needs. That is how they are obligated to set the quota, based on legitimate medical need. And every year, they've raised the quota because the standard of care was changing.

Now, to his credit, Mr. Rannazzisi fully acknowledged that he approved major quota increases. And when Ms. Singer asked him why he approved such large increases over his 10 years as the head of DEA enforcement, he said it was to ensure that there was enough quota for patients.

So as more prescriptions were going out of pharmacies and hospitals, the quota was increased by the DEA to meet the patients' medical needs.

Now, stepping back, Your Honor, given where Cardinal Health sits and their vantage point, the increasing orders that Cardinal Health was receiving made perfect sense.

If Cardinal Health looked downstream, it saw what everyone else was seeing; that doctors across the country were prescribing more opioids.

And if it looked upstream, it saw that the DEA was publicly saying that 99 percent of doctors are prescribing opioids appropriately and the DEA was finding that legitimate medical need was increasing year after year and raising the quota.

So there is absolutely no reason, Your Honor, why the increasing orders pursuant to the changing standard of care and the DEA quota, there's no reason why those orders should have been alarming to Cardinal Health.

Now, the plaintiffs have focused on the Cabell/Huntington volume. And they've said, well, maybe the standard of care explained what was happening nationally, but you can't explain the volume coming into Cabell and Huntington. And I think they're wrong about that.

Now, before we unpack the reasons why and the evidence that we saw at trial, I just want to remind Your Honor of one thing.

And that is as Dr. McCann testified, going back as early as 1998, DEA has published on its website the volume of prescription opioids shipped down to the three-digit zip codes.

So back to 1998, that data was available to anyone who wanted it, including city and county officials.

But before this lawsuit was filed, no one, not the DEA, not the State of West Virginia, not the plaintiffs, ever said that the raw volume of opioids being shipped to Cabell or Huntington was too high or that distributors should have shipped fewer pills.

So let me turn to five pieces of evidence from trial that inform specifically the volume shipped to Cabell County

and Huntington.

Now, the first one is the one that, that I went over with Your Honor. And I think taking a look at the chart, one of the charts that Mr. Nicholas showed you yesterday, this chart described the prescribing in Cabell/Huntington from Ms. Keller lining up with the distributions from Dr. McCann.

But if we keep going to the next slide, we see the calculation that was actually done by Ms. Keller. And I think on cross Ms. Wicht asked her to do the math. And Dr. Keller got the math right when she did it on cross.

And what she calculated, that the prescriptions that she had information on came to -- for 2006-2014 in Cabell County, 141.2 pills per person, and that the distributions that Dr. McCann had calculated came to 142.19 pills per person.

I think, as Mr. Nicholas said yesterday, that number right there, or those two numbers right there are absolutely amazing in terms of how they match up basically to the pill. And to her credit, Ms. Keller made that concession, that they match up to the pill.

Now, what's also remarkable is this conclusion is consistent with something Mr. Rafalski also said.

Mr. Rafalski's testimony was that he was not aware of any pills, any pills shipped by McKesson, ABDC, or Cardinal

that ended up doing anything other than filling prescriptions written by licensed prescribers.

The second piece of evidence that relates to Cabell and Huntington. The evidence was overwhelming at trial, Your Honor, and I won't belabor it, that the prescribing that was done nationally, but also in Cabell and Huntington, was done in good faith, and virtually all the prescriptions were legitimate.

So we've already seen Mr. Rannazzisi with the reference to 99.5 percent of prescribers not over-prescribing. And we're familiar with this quote, but I want to remind the Court that Dr. Rafalski -- or Mr. Rafalski also said the same thing. Mr. Rafalski also agreed that 99 percent of doctors prescribe opioids for legitimate medical purposes.

Now, one piece of evidence we haven't seen that often so far, Your Honor, is that in 2006 the DEA went so far as to say in the Federal Register that, quote, nearly every prescription issued by a physician in the United States is for a legitimate medical purpose in the usual course of professional practice. And not a single witness disputed that.

And as Your Honor knows, to the contrary, witness after witness on the plaintiffs' side agreed that the vast majority of doctors prescribed opioids in good faith based on the information that they had at the time.

So, again, Dr. Waller said doctors who were prescribing opioid medications for chronic non-cancer pain were acting in good faith. Even Dr. Keyes said the overwhelming majority of doctors prescribed opioids to their patients in good faith. And then our local witnesses also agreed that this was true in Cabell and Huntington.

So Dr. Yingling testified that the use of prescription opioids in Cabell County is within the bounds of medically accepted practice.

In Huntington Mayor Steve Williams said that he even believed that the vast majority of doctors in Cabell County and Huntington thought they were prescribing opioids appropriately. Another key piece of evidence, Your Honor, that informed the volume in Cabell and Huntington.

Another way that you know that the volume shipped to Cabell and Huntington was reasonable is because the magnitude of the increase in distributions into Cabell and Huntington over time was the same as the magnitude of the increase in West Virginia, as well as the nation.

So to the extent that Cabell and Huntington ended at a higher rate or at a higher number, Your Honor, that's because they started higher.

So let me explain this slide. So the far left slide, Your Honor, shows distributions nationwide. These are Dr. McCann's charts, not our charts. And the middle bottom

shows distributions in West Virginia. And the far right shows distributions in Cabell and Huntington. And up top we have the same nationwide -- the DEA quota chart we were just looking at.

And what Dr. McCann showed us is that distributions in Cabell and Huntington rose by the same factor as distributions into West Virginia and nationally, and even by the same factor as the DEA quota.

So let me show you his testimony. Dr. McCann told us that from 1997 to 2010 there is a ten-fold increase across each of these charts, overall quota, West Virginia and Cabell/Huntington. Everybody increased at the same ten-fold rate.

Well, if the trend is the same, why did Cabell and Huntington end up higher on a per capita basis compared to the nation or even West Virginia?

And the evidence shows it's because they started higher. Even in 1997, Your Honor, before any of the conduct that plaintiffs allege was wrongful in this case, per capita opioid distribution and, therefore, prescribing was already higher in Cabell and Huntington than it was nationally or statewide.

And that's because of the fourth piece of evidence, Your Honor. West Virginia and, in particular, Cabell and Huntington, have higher rates of pain-causing conditions

and, therefore, higher rates of prescribing. And that's always been the case, or been the case for a significant amount of time.

Now, Drs. Gupta and Deer, who know these populations well, each testified about this.

So Dr. Gupta told us that West Virginia ranks number one in the country in total prescriptions per capita. So not opioid prescriptions, but number one in the country in total prescriptions per capita. So West Virginia doctors prescribe more medications overall.

As of 2016 -- this is from one of Dr. Gupta's reports -- the average West Virginian received 20.8 prescriptions per year which was far higher than the national average of 12.6 prescriptions per year.

And Dr. Gupta also testified that West Virginia has higher rates of pain-causing conditions compared to other parts of the country which leads to more opioid prescribing.

And he had a presentation that we went over with him that showed West Virginia's higher rates of pain-causing health conditions.

So West Virginia has ranked in the West Virginia charts number one in the nation in arthritis, number one in cardiovascular disease, number one in obesity, number one in COPD, and number one in high blood pressure.

It's ranked number two in diabetes and number two in

depression, and number three in cancer.

Now, the additional part of the explanation for some of these numbers was provided to us by Dr. Deer. West Virginia has an older population, he told us, which tends to suffer, of course, from more pain-causing conditions.

And he also told us that West Virginians work in physically demanding jobs, more so than their counterparts in other states. So there are more work-related injuries.

And even Dr. Keyes agreed with that. Dr. Keyes was cross-examined on an article that she published before she became an expert in this litigation on why people in rural areas abuse opioids more.

And she said, like Dr. Deer, that rural populations are older and have higher rates of chronic pain and injury. And that's why she would expect to see higher levels of opioid prescribing in West Virginia than in other states.

We also heard from Dr. Deer and then Dr. James Hughes on insurance providers, including Medicaid and Workers' Comp. And we've heard how those providers restricted non-opioid pain treatment which led to patients staying on opioids longer.

Dr. Hughes explained that West Virginia had unusually limited coverage of, for example, chiropractors and physical therapy, and that other states by contrast covered much more and made it easier to get non-opioid alternatives.

And all of these reasons ultimately magnified why the numbers in Cabell and Huntington were higher. And if we focus in just on Cabell and Huntington, I think we heard testimony from Mayor Williams that in 2008 the CDC reported that Huntington, unfortunately, had the worst health rating of any city in America and had higher -- had the highest rates of certain conditions relative to any other city in America. And Dr. -- Mayor Williams told us when he was here testifying that all of that was true.

Another piece of evidence we heard from Dr. Yingling is that people from neighboring counties actually come to Huntington for medical care which helps to raise the prescribing rates in the Huntington/Cabell area.

And Dr. Yingling called Huntington a hub of healthcare and noted that it had several hospitals and healthcare centers which, of course, one of them is the V.A.

Let me make one final point on the volume as it relates to Cabell and Huntington, Your Honor.

The overall ratio of Cardinal Health controlled substances shipments coming into Cabell and Huntington fit perfectly with the DEA's expectations. The ratio of controlled substances to all medications shipped is a key factor recognized by the DEA for distributors evaluating pharmacies.

Mr. McDonald, our data expert, looked to statements

from the DEA that a distributor could expect controlled substances to be anywhere from 5 to 20 percent, 5 to 20 percent of its shipments to pharmacies.

Mr. McDonald did the calculation. And he calculated that Cardinal's number for Cabell and Huntington was 14.9 percent, so well within the DEA expected range of 5 to 20 percent. And opioids -- if we look just at opioids, they were just 7 percent.

So Cardinal Health's opioids shipments to Cabell and Huntington were completely reasonable given the total number of prescriptions that doctors wrote for all medications.

To sum up on volume, Your Honor, the standard of care for pain management changed drastically. Doctors in West Virginia and around the country prescribed opioids far more often than they had in the early '90s. And nearly all of them did so in good faith. And they could have been disciplined if they hadn't.

West Virginia and Cabell County had higher than average opioid prescribing rates, but they also had higher rates of prescribing for all medications. And that's because they had some of the worst overall health statistics in the country.

So controlled substances were not an unusually high percentage of our distributions in Cabell County. And over the entire time span in question, Cabell County's rates of

opioid prescribing grew at exactly the national average.

The number of pills we distributed there was exactly the number that doctors prescribed. And not one word, Your Honor, in the summary that I just gave you is disputed.

Plaintiffs have given the Court no basis whatsoever to find that Cardinal's distribution volume in Cabell and Huntington was unreasonable.

Now, that's volume, Your Honor.

Did the plaintiffs show that our systems, our Suspicious Order Monitoring Systems allowed orders to be filled there?

THE COURT: Do you want to take a break, Ms. Mainigi?

MS. MAINIGI: Yes. I think that would be wonderful, Your Honor.

THE COURT: Okay. This looked like a time to do it.

MS. MAINIGI: This is a perfect time. Thank you, Your Honor.

THE COURT: All right. We'll be in recess for about 10.

(Recess taken from 10:00 a.m. until 10:14 a.m.)

MS. MAINIGI: Thank you for the break, Your Honor.

During the break, I was reminded by some of my smarter colleagues of Dr. Murphy's testimony. I think you had asked

or suggested that some economists might say supply affects demand. But I think you probably remember that Dr. Murphy addressed that specific question --

THE COURT: He did.

MS. MAINIGI: -- for this industry. And you remember it better than I do, Your Honor.

THE COURT: I didn't ask him the question because I didn't know how to pronounce Say Fa (phonetic). I don't know French so --

MS. MAINIGI: Well, I can't pronounce it either, Your Honor, unfortunately. But I do, I do know now and have been reminded that Dr. Murphy testified that in this industry, the industry that we're in, our distribution does not drive demand.

And, and the chief reason for that, obviously, is because a patient cannot get a prescription without -- cannot get the medication without a prescription. And that was, I think, Dr. Murphy's testimony pretty clearly.

So, Your Honor, where I had -- I'm sorry, Your Honor. Did you have another question?

THE COURT: No. You can go ahead.

MS. MAINIGI: Thank you.

So let me shift over. I know I said earlier that the, the plaintiffs did not spend a lot of time on our systems, our Suspicious Order Monitoring Systems. But I do want to

outline for the Court some basics related to those systems.

So you can think of Cardinal Health system in basically three eras. And I think you heard a little bit about this when Mr. Mone testified.

So you've got pre-2008. You've got 2008 to 2012. And then you've got 2012 through the present.

And until 2008, the Cardinal system was led by a former law enforcement officer named Steve Reardon. And he had been with the company since the 1980s.

And under Mr. Reardon's leadership, Cardinal Health operated a Suspicious Order Monitoring System that was very similar to the other programs around the country. It had a couple of components. It had suspicious order reporting and due diligence on the pharmacy customers.

And Cardinal sent monthly reports to the DEA called Ingredient Limit Reports. And those Ingredient Limit Reports were based on a computer program that compared customer purchases to pre-determined limits.

And if a customer's purchase exceeded the limit, then their order went into the report. And then the report itself went to the DEA after the orders were shipped.

Now, there was another component that involved folks called pickers and checkers. And it was their job to also identify excessive orders based on their own particular experience in the distribution centers with customers.

And orders that they identified could be stopped right there at the distribution center and reported to the DEA before they were shipped. So the distribution center could stop orders it thought might be excessive or suspicious.

The key takeaway, Your Honor, I think for the pre-2008 system is that the DEA understood Cardinal's program and it was completely consistent with what other distributors were doing and the DEA expectations at the time.

So the Court has the depo designation, deposition designation for Mr. Michael Mapes who was the DEA diversion investigator. And he testified about the submission of these Ingredient Limit Reports. Some companies called them Excessive Purchase Reports.

And I think those were the reports that were part of the ABDC system that Mr. Nicholas talked about yesterday. And as Mr. Nicholas told you, the DEA expressly approved ABDC's program which, like Cardinal Health's program, reported suspicious orders after they had been shipped until that 2008 forward time period.

Let me go ahead and just play the clip where Mr. Mapes testified to that.

(A video clip was played as follows:)

"Was the submission of Excessive Purchase Reports in your experience standard practice in the industry?

It was.

And in your experience, DEA viewed those reports as compliant with the Controlled Substances Act?

Yeah. I viewed those as compliant with the regulation for suspicious orders."

(Video clip concluded)

MS. MAINIGI: And I think that there is other such testimony in the record as well.

But Mr. Mapes who had responsibility, along with Kyle Wright, over several of the distributors, several of the major distributors, certainly testified that he viewed the process that was followed in the pre-2008 time period to be consistent with the DEA expectations.

Now, I think, as Your Honor has heard in the first few weeks of trial, toward the end of 2007 the DEA changed its expectations about shipping suspicious orders and about Suspicious Order Monitoring Systems as well.

And as Mr. Nicholas told you, AmerisourceBergen developed a next generation monitoring program in response to this new DEA guidance. And ABDC and the DEA jointly presented that program at an industry conference in September of 2007.

The DEA used that presentation, as we heard, to tell the industry what it wanted to see in monitoring programs going forward.

And the biggest change, as you heard in the early weeks

of trial, was that the DEA from that point forward no longer wanted distributors to ship suspicious orders.

And, so, when the DEA announced in September, 2007 that it wanted ABDC's new system to be the model, Cardinal Health complied.

Now, what I want to show Your Honor is an email, September, 2000 email -- 2007 email from Mr. Reardon. So we're about to go through a transition period. But Mr. Reardon sent this email after the conference he had just attended.

And, in fact, it says final summary of DEA meeting dated 9/7/07. The email itself is seven days later on September 14th.

And among other things, Mr. Reardon tells his colleagues back at Cardinal, "DEA is setting a new standard with which we must comply."

And then he explains why.

And then he says also, "DEA referred to the ABC program as the new industry standard. I will be setting up a meeting to initiate discussions on this topic in the near future."

So Cardinal, after that point, set about revamping its Suspicious Order Monitoring System to essentially echo what it had seen in the presentation at the September, 2007 conference.

And in furtherance of that, in December, 2007, Cardinal hired Michael Mone who Your Honor heard from live here at trial. Mr. Mone came in to supervise the anti-diversion program and the on-going enhancement of that program.

And he was an important addition to the Cardinal team because as Your Honor may recall, he was both a pharmacist and a lawyer, and he had run a state Board of Pharmacy and practiced in the state AG's office.

He had also -- while he had the other roles, he had helped to create one of the first state prescription drug monitoring programs in the country.

So when he came in and took over, Cardinal Health was already in the process of implementing what it had learned at the September, 2007 conference. And he told us on the stand about essentially the three components of the Cardinal Health system.

The Know Your Customer component involved a detailed evaluation and due diligence effort on new customers, as well as on-going diligence of existing customers. A new customer approval was not automatic. Cardinal Health rejected some customers because of diversion concerns.

The second piece was electronic order monitoring. And as part of that piece, a customized threshold for each drug family was set for each customer. And the system now automatically held orders over the threshold.

And then the held orders were evaluated by the anti-diversion team which included several pharmacists.

Then when the investigation ceased, there were regular site visits that were made to the customer by former police and former investigators from the DEA, Medicaid, and Board of Pharmacy.

And then there was an analytical -- an analytics team that was also set up to create reports, evaluate thresholds, re-examine thresholds.

So Cardinal moved quickly to get into place a new system that essentially embraced the components that the DEA said it wanted embraced.

And all of this information, Your Honor, is in the standard operating procedures that Mr. Mone testified about. And, again, just like in the prior time period, Cardinal kept the DEA up-to-date on what it was doing.

So in 2009, as Mr. Mone testified, the chief of the DEA's regulatory section was a woman named Barbara Boockholdt. And Mr. Mone told us early in 2009 he met with her and her team in person for a full week. And they reviewed the company's updated system in detail.

Mr. Mone told us that he covered with her how thresholds were set and identified and how the company was handling suspicious orders. And to the -- I think I heard some reference yesterday from the plaintiffs about the

multiplier for thresholds.

To the extent that a multiplier was used as part of our threshold setting system, the DEA was aware of it and did not raise any concerns.

And Mr. Mone told us that at the end of the week, the DEA didn't offer a single complaint or ask for a single change. And Mr. Mone stayed in touch with Ms. Boockholdt after that and talked to her regularly about whatever improvements the DEA was looking for from distributors.

Now, the DEA guidance that came out in a variety of ways evolved again in the 2012 time period. And the DEA changed its focus in that time period to numbers; data analytics and quantitative measurements.

And, so, Cardinal Health added new metrics to analyze if pharmacy customers changed its threshold setting procedure. And because of the new focus, Cardinal brought in someone that had that specific expertise, Todd Cameron who has run our anti-diversion program since 2012.

Now, Mr. Cameron may not look familiar to you, Your Honor. The plaintiffs had asked us to make Mr. Cameron available to testify in their case, and we did make him available to testify. He was here in Charleston waiting to take the stand when plaintiffs let us know that they no longer wanted to put him up ultimately as a witness.

The bottom line, Your Honor, is that the plaintiffs

have essentially presented no evidence and have no complaints, as far as we have heard during this trial, about Cardinal Health's program after 2012. They didn't mention it in opening, and they haven't mentioned it in closings either.

So I'm not going to spend too much time on the 2012 system, but we'll cover the 2012 system in our findings of fact ultimately so that Your Honor has a complete record.

But, essentially, the components of the system stayed the same per the DEA guidance. There was still a --

Matt, if we could put up that slide.

There was still a Know Your Customer component and electronic order monitoring component and an investigation component. But the various types of criteria that were used were certainly altered to comply with the expectations from the DEA.

And Cardinal put together a committee also called a Large Volume Tactical and Analytical Committee that included anti-diversion professionals and senior Cardinal officials. And its entire purpose was to review large orders from customers as they came through.

And then the diligence files. The diligence files in evidence also show Cardinal Health continuing its practice of regular site investigations and visits of its customers.

And as we'll state in our findings of fact, Your Honor,

Mr. Cameron has presented this program to the DEA several times, the current program at -- as it has evolved. And there's no evidence that DEA has found any fault with that program since 2012.

Now, what have plaintiffs chose to focus on then when it comes to the SOMS system? They haven't gone into the specifics. What they do is point occasionally to Cardinal's 2008 and 2012 Settlement Agreements.

But there is no connection, Your Honor, between those agreements and West Virginia. There is not evidence through those agreements of any sort of systemic failure or any unreasonable conduct related to Cabell County or Huntington.

Let me review those two agreements with you.

The 2008 DEA action had to do, Your Honor, with shipments to internet pharmacies which are not at issue in this case.

And it had to do with shipments to internet pharmacies from our distribution centers in Texas, New Jersey, Washington, and Florida. And none of those distribution centers shipped to Cabell/Huntington as Dr. McCann admitted when he was on the stand.

The Wheeling distribution center is the only one that shipped to Cabell and Huntington. And it had never had a DEA enforcement action.

The 2012 DEA action, Your Honor, had to do with just

four specific pharmacies, so not four distribution centers even, but four specific pharmacies in Florida that were served by our Lakeland, Florida, distribution center.

And before the DEA even took action, we had already terminated two of those four pharmacies. And to give you some context, Your Honor, those are four pharmacy customers out of our 29,000 pharmacy customers.

Now, what else did they do besides the settlement agreements? The plaintiffs continue to cite to Mr. Rafalski. Now, we already know -- in our view, he already has a major *Daubert* problem and we've obviously briefed that issue.

But even if Your Honor does not exclude his testimony, his testimony is just not credible and far too generic and unsupported to be the basis for this Court to find unreasonableness.

So taking a look at what Mr. Rafalski actually did or did not do, to be more precise, Mr. Rafalski admitted that he didn't look at all the due diligence for the orders flagged by his methodology. Only some he said. But we know he didn't even look at the initial orders flagged under his methodology to see if he could call them suspicious.

He conceded he had no idea how many of the orders he flagged were investigated and cleared by Cardinal Health. He doesn't know if we investigated 0 percent or 100 percent

of them. And he didn't even try to figure it out.

He conceded, Your Honor, that he didn't know which orders were actually suspicious and should have been reported to the DEA, or if there were any of those orders at all. He had no idea whether there was any single suspicious order that we did not report.

And he conceded he did not evaluate how many of his flagged orders went to meet legitimate medical needs. So he also doesn't know which orders, if any, were actually diverted.

He didn't do the work he needed to do, Your Honor, is the basic bottom line. And he didn't do that work for any of the three distributors.

Now, just briefly on his methodology. I think it can be summed up pretty well with what's on the screen. No one's ever used them in the real world, his methodologies, not the DEA or any distributor. He made them up for this litigation.

After making up six of them, he said there were four of them he would not use. And he conceded that there's a huge number of other flagging systems that could also comply with the law.

Now, when Mr. McDonald applied Mr. Rafalski's 90 percent methodology, his Methodology A, he testified that Mr. Rafalski's Method A flagged 90 percent of anything. So

any series of numbers, whether it's daily temperatures, random rolls of the dice, and shipments of all kinds of medications, his methodology was a one-size-fits-all methodology.

And Mr. Rafalski conceded that he views these exact same methodologies with equally astounding results in litigation in Ohio and New York. So there's nothing special or different about his analysis in Cabell and Huntington.

Now, let me come back to due diligence because that's something that the plaintiffs have tried to spend some time on. The only thing that the plaintiffs mentioned yesterday about Cardinal Health, Your Honor, the only thing was a reference to due diligence and Medicine Shoppe. So I want to spend a little bit of time going through that with you.

Mr. Rafalski admitted he obviously had not looked at the due diligence files in their entirety. And just to remind Your Honor of the testimony from Mr. Mone, Mr. Mone was asked about due diligence when he came to testify.

And as Mr. Mone testified, Cardinal Health did due diligence on every order that hit a threshold and did on-going due diligence on customers from Know Your Customer as well as site investigation.

Now, Cardinal has 34 -- or during this time period had 34 customers in Cabell and Huntington. And, again, at trial and yesterday the plaintiffs have discussed essentially one,

Medicine Shoppe.

And I think they've essentially tried to allude that there was no due diligence done for Medicine Shoppe. But, Your Honor, this right here is the due diligence file for Medicine Shoppe that was produced to the plaintiffs. And this is P-42116 for the record.

This document has hundreds of pages of diligence all the way back to the questionnaire that Medicine Shoppe filled out back in 2008 when it became a customer of Cardinal.

Another thing that this file contains is several anti-diversion customer profiles. So when an order hits a threshold, Your Honor, Cardinal Health's anti-diversion team reviews the information that's shown here -- type of information that's shown here to determine whether to release the order or to report the order as suspicious.

And the type of information that they analyze and look at includes one of the things I mentioned earlier which is the overall controlled substance percentage to the, to the entire prescription percentage; the volume of particular categories of drugs; the number of previous threshold events that the customer has had, so basically their track record; and then their overall purchase data by month for that drug family.

In later periods under Mr. Cameron, for example, this

type of data was enhanced and different types of analytics were used. But there is multiple types of due diligence of this variety that is in the file. So it is astounding that the one thing that the plaintiffs point to is an unexplained two-word phrase in an email that says "black hole."

They didn't explain to you what that said or what that meant. They didn't call the person at trial who wrote that email. But what we do know about the Medicine Shoppe is that there is a long history of diligence on this customer.

Mr. Farrell told you yesterday that after the black hole email, nothing happened. That's wrong.

Right after that email, Cardinal Health immediately followed up with a full site investigation. And that's documented in the file. And Mr. Mone actually told us about that at trial. He said the black hole email was reviewed by him.

The anti-diversion team reviewed this investigative report, Your Honor, which is in the file and found no evidence of diversion.

Other site visits at Medicine Shoppe confirmed the same thing. There was a full investigative visit in December of that year and again in -- that was 2012, Your Honor. So they went back again that year. And then there was also a full investigative visit that's in the file for 2015 and 2016. And each time, the investigators found no evidence of

diversion.

Now, we also heard from Jesse Kave who was Cardinal Health's sales representative. And he testified that he monitored his customers for signs of diversion. He called on Medicine Shoppe for 12 years, and he lived only a half an hour away from Medicine Shoppe.

He got to know the pharmacists there. He found them to be professional. And he did not have concerns about diversion which is a fact that he documented repeatedly.

Now, another witness that the plaintiffs didn't call but had under subpoena during the entirety of their case was, in fact, the representative from Medicine Shoppe. So we didn't get a chance to ultimately cross-examine that person, but the, the plaintiffs had the opportunity to bring that person in.

And as I stand here today, Your Honor, Medicine Shoppe remains a licensed pharmacy in good standing with the State of West Virginia as well as the DEA.

So, Your Honor, with respect to the Suspicious Order Monitoring System, to the extent that the plaintiffs even covered that type of information, there is just absolutely no evidence that Cardinal Health acted unreasonably in that context.

Let me shift over to causation, Your Honor.

The plaintiffs have to prove that they caused the

alleged harms, and here they cannot.

Now, as our briefing has covered with Your Honor, causation has two components; but for causation and proximate causation. And our position is that the plaintiffs have proven neither.

On the but for causation, or sometimes called cause in fact prong, plaintiffs have to show that the alleged harms would not have happened without Cardinal Health's alleged misconduct.

So they had to prove here, Your Honor, that if Cardinal Health had done something different, the problems in Cabell and Huntington never would have happened.

When they filed their brief on causation this weekend, they had no answer to the cause in fact argument that we raised. And they gave no answer to it in closing yesterday. They didn't even mention but for cause.

The bottom line is that the same number of opioid prescriptions would have been written and filled in Cabell and Huntington even if Cardinal Health had not existed.

Doctors, as we know, decide how much to prescribe. The DEA decided how many opioids would be available for dispensing.

Mr. McCann told us that there were 35 other distributors doing business in Cabell County. Our pharmacy customers could have ordered from any of them.

Mr. Rafalski told us he didn't know of a single instance where a distributor cut off the pharmacy and the pharmacy didn't just switch to a new distributor. Only the DEA can cut off a pharmacy.

So on the evidence that's before the Court, Your Honor, even if there had never been a Cardinal Health, doctors in Cabell County would have written the exact same number of prescriptions. Pharmacies would have filled them. They would have ordered the exact same amount of medications from distributors. And distributors would have shipped them.

If the same thing would have happened in the absence of our very existence, then by definition, there is no but for causation.

Now, they say we should have done more due diligence. But they have not shown you a single order that would have or should have been rejected if we had done more due diligence.

They say we should have sent more reports to the DEA. But the evidence shows that the DEA didn't even act on the reports we sent them already. And, so, this is a basic legal proposition, Your Honor. And it's not a proposition that is necessarily apparent in every case, but, but it is apparent in this one. They say we should have done certain things we didn't do, but they haven't proven that if we had done them that anything would have been different. And if

they cannot prove that, there is no liability for causation purposes.

Now let me shift over to proximate cause. And let me start with the standard for proximate cause.

Plaintiffs have to show the alleged harm is a direct consequence of the alleged conduct. And that's the test, as Your Honor knows, that Judge Copenhaver applied last year specifically in the context of the prescription opioid litigation, the *JCAHO* case. And as you know, he dismissed the case on 12(b)(6) grounds for lack of proximate cause.

Now, with respect to the Copenhaver case, we will address that case, Your Honor, more fully in our proposed conclusions of law. But one of the points that plaintiffs focused on is foreseeability. And foreseeability alone is not enough. It's one part of the analysis, but it's not the entire analysis.

And West Virginia law is clear that the Court has to find that the defendant is a direct, not a remote, cause. And that's what Judge Copenhaver said in the *Joint Commission* case. And Judge Chambers said the same thing in the *Teamsters* case from 2013.

Now, Your Honor asked yesterday how the *City of Charleston* case is different from this one. And we think it's the same. We don't view it to be different.

Mr. Majestro was asked a follow-up question on that or

answered a follow-up question on that. And Judge Copenhaver, to be clear, did not find that there would be proximate cause as it relates to distributors. He didn't make any finding as it relates to distributors.

But what he did say in a case about what caused the opioid epidemic was that the Joint Commission was too remote because of multiple actors in the chain, including criminal actors and doctors exercising their medical judgment.

And if this trial has established anything, Your Honor, it's that those facts are equally present here.

So after a full trial, plaintiffs have failed to prove their basic theory of causation.

Coming back to what their theory is, their theory is that Cardinal Health caused the volume of opioids that entered Cabell and, therefore, caused the diversion and misuse of the prescription opioids in Cabell and Huntington, and ultimately caused the abuse of heroin and fentanyl in this jurisdiction.

But they did not actually prove any of those things. So if we start with volume, everything I said about volume and reasonableness, Your Honor, applies equally to proximate cause.

But there's no evidence that in any way Cardinal Health caused the volume of prescription opioids that entered the market. As we've talked about, the volume comes from the

number of prescriptions doctors write and the upper limits that the DEA imposes in the form of quota. And Cardinal Health has no control over either one of those.

And as we're thinking about it, it's worth remembering what the plaintiffs claim about why the standard of care ultimately changed. And the plaintiffs in their complaint don't say it was the distributors who changed the standard of care. They say it was manufacturer marketing.

So looking at the admissions that are in the plaintiffs' complaint, the plaintiffs say manufacturer marketing defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket.

Mayor Williams agreed that it was the manufacturers' deceptive marketing that caused, their word, caused the prescribing of opioids to skyrocket. And, of course, we already know that the city also blamed, in addition to the manufacturers, the Joint Commission for changing ultimately the standard of care.

The city said that the Joint Commission teamed with Purdue to cause the opioid crisis by pushing pain as the fifth vital sign and increasing prescribing. So that's prescribing.

There's also no proof, Your Honor, that we caused diversion or misuse. And, again, there are just too many

links in the causal chain.

First, you've got to have a state and federally licensed doctor prescribe the medication. Then you've got to have a state and federally licensed pharmacy dispense the medication. Then someone has to divert it. And then someone has to use it illegally.

So that prescribing link has nothing to do with us. We never see a prescription, Your Honor. Our pharmacy customers place bulk orders from us so they'll have an inventory to fill prescriptions they expect patients will bring to them in the future.

We have to way of knowing whether the medications in those orders will go to terminal cancer patients or post-surgical patients or injured coal miners. That's up to the doctors to decide.

Now, remember what Dr. Werthammer told us. He had sent an email to the Mayor and other leaders that said, "Unfortunately --" and this is from 2016. "Unfortunately, it was not big pharma who wrote the prescriptions. It was me and my colleagues. Joe."

And his colleague, Joseph Shapiro, Dr. Shapiro, who's the Dean of Marshall's medical school, wrote right back. "We had some help. Pain as the fifth vital sign comes to mind."

The medicine cabinet diversion that happens after the

medicine leaves the pharmacy isn't caused by anyone in the DEA regulated supply chain. Either the patient who gets the medication -- the patient either sells it or gives it away. And that's a crime. Someone comes along and steals it, either uses it or sells it, and that's a crime. And, finally, someone has to use the illegally diverted medication, and that is also a crime. And Cardinal Health can't stop any of that from happening.

Now, even Mr. Rafalski agreed that medicine cabinet diversion is the responsibility of the patient, not the distributor who supplies the patient's pharmacy and has no control.

Now, turning to illegal drugs, which has been a problem in Cabell and Huntington for a significant number of years, the plaintiffs have not proven we caused heroin and fentanyl abuse. Obviously, heroin and fentanyl, illicit fentanyl are distributed by drug traffickers, not Cardinal Health.

And the idea of holding us liable for the criminal conduct of drug dealers a decade after they last complained about anything happening with our Suspicious Order Monitoring Systems is completely and utterly remote.

Now, plaintiffs when they use the word "opioid" have been imprecise to say the least. They've used the term broadly. And they use it broadly generally to encompass illegal drugs.

So take, for example, Ms. Kearse spoke yesterday about the West Virginia outbreak report and featured that report in her closing. And that was one of Dr. Gupta's reports.

But that report, Your Honor, from 2016 was entirely about the string of overdoses in Huntington from fentanyl-laced heroin. It had nothing to do with prescription drugs.

Now, we heard testimony that Cabell County and Huntington have had an enormous problem with illegal drug traffickers. And there's a lot of that in the record and I imagine Mr. Hester will cover that.

But the city has admitted that the problem dates back to at least 2002 and that relates to economic cuts that were made in that time period.

Because of that knowledge and recognition about the prevalence of illegal drugs in Cabell and Huntington and those being the driving force behind substance abuse issues, the plaintiffs have tried to fill the hole that they have on causation with a gateway theory. And that's the idea that prescription opioid use causes the use of illegal opioids like heroin and fentanyl.

In the first instance, Your Honor, gateway is irrelevant to liability. Gateway does not show that Cardinal Health caused anyone to use heroin or fentanyl. And even if there is a gateway effect from the use of FDA

approved medication, the individual use of illegal drugs would be far too attenuated from our conduct and far too remote under the case law to establish liability.

But just so that the record is straight on gateway and the evidence that the Court heard, I just want to cover a few points on the gateway theory.

Your Honor has heard about the 80 percent number. The 80 percent figure that plaintiffs throw around, Your Honor, is about illegal misuse or non-medical use of prescription opioids, not legal use.

So there's the Muhury study which says four out of five heroin users previously used prescription opioids. But as Dr. Gilligan explained, the Muhury study, which is the primary source that the plaintiffs point out, looked at prescription opioid misuse, not medical use, and it's only looking at people who use prescription opioids illegally.

Second, even among people who misuse prescription opioids, the percentage who transition to heroin is very low. And Dr. Gilligan and Dr. Keyes testified that the vast majority of people who misuse prescription opioids do not go on to use heroin. Only 3.6 percent of them do.

Third, the reality is that people who abuse drugs, abuse lots of them, not just one kind, so illegal drugs begets illegal drugs. And the Muhury study showed almost all illegal drug users have used a wide variety of drugs in

their past. And even Dr. Keyes agreed with that.

Dr. Gilligan also agreed with that. And if you look at his actual testimony on this issue, he said that people transition to heroin from all kind of drugs, cocaine, crack, marijuana and other drugs.

Now, Dr. Murphy. He said the research shows that some people are just simply prone to abuse drugs. And that's certainly consistent with everyone's life experience. They abuse whatever substance is available and often lots of different ones.

And Dr. Waller told us, the addiction specialist, why that happens. He said that all addictive substances have the same final common pathway in the brain and they all affect dopamine. So it's not a surprise that people with addiction will abuse multiple substances.

It's not about a gateway from one drug to another. It's an overall addiction problem, which is a point that Dr. Judith Feinberg, plaintiffs' expert on IV drug use, agreed to. And she called it a polysubstance opioid addiction problem. And she said further that the real problem of addiction lies in the social and economic fabric.

Stephanie Colston agreed. And she says that the country's not suffering from an opioid epidemic per se, but from a crisis of polysubstance use and substance use disorder.

Here's the fourth thing about gateway. The numbers show no link between prescription opioid distribution and illegal opioid overdose deaths.

So Dr. Murphy showed you this scatter chart. And literally the dots are all over the map. There is no trend. He analyzed the data and said not only is there no causal relationship, there's not even a correlation.

And he concluded that places, as an example, that have high shipments of prescription opioids did not necessarily have higher death rates from illegal opioids.

So the gateway theory is both irrelevant to liability and contradicted by the evidence.

Another piece of evidence, Your Honor, that there is no causation here outside of this litigation is that the plaintiff -- neither the plaintiff nor the state say that the distributors caused the opioid problem.

So for the past 10 years, one committee after another has studied this issue. And they've written report after report after report. And there's a stack of those reports in evidence at this point, Your Honor. And not one of them point to any misconduct by distributors as a cause of the opioid epidemic. And there are a number of reports that are in the record right now.

So you've got the city's 2011 drug market intervention report that blamed the problem on police budget cuts and the

influx of drug dealers.

And the city's 2015 strategic plan did the same thing. It had a prevention prong that focused on illegal drug dealers.

The 2016 Social Autopsy that we looked at with Dr. Gupta, I think Mr. Farrell said that yesterday -- yesterday said that it proves diversion. But it says nothing about distributors. The report focused on doctors and their prescribing. And 2016, of course, was the year that the CDC guidelines came out.

The city's 2017 strategic plan. In the prevention recommendation it focuses on drug dealers.

And the city's 2018 report to the National League of Cities, that's the one that pointed to the poor health. It doesn't say anything about distributors.

And then Dr. Gupta's 2018 opioid response plan. Like Dr. Gupta's other reports, these recommendations focused on prescribers.

To sum up on proximate cause, Your Honor, let me walk through the causal chain and walk you through what the theory would be.

So the plaintiffs' theory is that if a patient suffered pain and a licensed doctor prescribed FDA approved opioids for that pain and a licensed pharmacist dispensed them and the patient had leftovers in the medicine cabinet and

someone got their hands on those leftovers and used them or sold them and a tiny fraction of those people later used heroin or fentanyl, which came either from a drug cartel in Mexico or China or via a drug dealer from Detroit operating in Huntington, that down the chain Cardinal Health should be liable for filling a bulk order, a bulk order from the licensed pharmacy.

It is much too attenuated, the chain of events, and is a good reason that Judge Copenhaver invoked proximate cause to dismiss the city's case against the Joint Commission. And there's a good reason that Judge Chambers rejected -- or adopted the proximate cause argument in that particular case related to the Teamsters.

And Judge Chambers in that case cited a vast array of intervening events, including also, just like Judge Copenhaver, the intervening medical judgment of doctors.

Plaintiffs have no basis to distinguish those cases. And now that we've heard the evidence, the absence of proximate cause is even more glaring in this case.

Now, Your Honor, Mr. Hester is going to cover abatement, so I only want to make one point on abatement. And that's the threshold issue with respect to abatement.

And the briefing on this is, is in our papers. But as a threshold matter, Your Honor, a Federal Court sitting in equity does not have the power to award equitable relief if

there is an adequate remedy at law. And that's the rule from the *Sonner* case. More than 10 courts since 2020 have followed that case. And that by itself, Your Honor, is a dispositive issue.

Now, in their brief filed Sunday, which I'm sure Your Honor has not had a chance to read, the plaintiffs say that the *Sonner* rule doesn't apply to them because they're governmental plaintiffs. And that's their main response. But that is wrong.

The exception they cite for that proposition only applies to sovereign governments like the United States or the State of West Virginia, not cities or counties. So that's a critical issue, Your Honor, that, that we feel this Court ought to take a look at.

Your Honor, there is a vast disconnect between the evidence we've heard and what the plaintiffs say in this case. Huntington's efforts on the opioid problem have been successful and it has cast itself as the City of Solutions.

And we've heard a lot of testimony about the financial resources that are already available to the city and the county, including Medicaid funding for treatment. We've heard about federal funding for substance abuse response. And, of course, there are cases other than this one that plaintiffs continue to pursue against manufacturers and others.

But what matters in this courtroom is not any of that. It matters what they have proven. Not one actual order we should have shipped has been proven in this courtroom. They have failed to prove that one actual customer should not have been shipped to.

They have failed to prove that one actual customer was diverting or that one actual customer has even been disciplined or lost their license.

There's been no failure of due diligence. There's not one prescription that was written because of something Cardinal Health did. And prescriptions being written based on the standard of care that the entire medical community was following, including the State of West Virginia, cannot be a basis for a finding of unreasonableness.

There's been a total failure of the plaintiffs' case on every disputed issue, Your Honor, and it compels a finding for the defense.

We are extremely grateful for the time and attention you have given to us in this matter, Your Honor, and the courtesies that you have given to all of us. Thank you for your time.

THE COURT: Thank you.

It's 10 after 11:00. When do you want to come back?

Mr. Hester, you don't want to start your argument now, do you?

MR. HESTER: Well, I'd rather not split it, Your Honor. And I can imagine it will make for a very late lunch. So I'm perfectly happy to come back whenever the Court wants after a lunch break.

THE COURT: I always consult Ms. Skinner on important matters like this one.

How about 12:30? Is that okay with everybody? All right. I'll see you at 12:30.

MR. HESTER: Thank you, Your Honor.

(Recess taken at 11:10 a.m.)

THE COURT: You may proceed, Mr. Hester.

MR. HESTER: Good afternoon, Your Honor.

THE COURT: Good afternoon, sir.

MR. HESTER: The plaintiffs' claim is foreclosed by the law and it's unsupported by the record evidence. This conclusion follows from five overarching points that I'm going to briefly summarize and then I'll discuss in more depth.

The first point is that the plaintiffs cannot establish proximate causation here for two central reasons. First, the increased volume of prescription opioids in the Cabell-Huntington community was driven by doctors' good faith prescribing decisions based on prevailing standards of care.

And, second, the plaintiffs' claimed harm in this case

is based overwhelmingly on diversion from the medicine cabinet or people's homes after opioids are prescribed and dispensed. Distributors are not responsible for this diversion and cannot control it, as the plaintiffs' own expert admitted.

So these intervening decisions of doctors who determine the volume of opioids and the intervening criminal acts of multiple actors who diverted opioids after they were prescribed defeats proximate causation on this record.

The second point. The plaintiffs cannot establish a public nuisance on this record where doctors were prescribing medicines in good faith to treat an important medical need and distributors had no ability to second-guess those prescribing decisions.

The third point. McKesson's shipments into Cabell-Huntington did not cause harm and plaintiffs have no evidence of improper conduct or diversion by any of McKesson's customers in Cabell-Huntington. Likewise, the plaintiffs were not harmed by any issues relating to suspicious order reporting because distributors always blocked orders likely to be diverted and distributors blocked all suspicious orders by no later than 2008. Blocked orders cannot give rise to diversion.

Fourth point. The current drug crisis in Cabell-Huntington is a crisis of heroin and illicit fentanyl

abuse and the abuse of other illegal drugs. The plaintiffs cannot establish proximate causation between the distribution of prescription opioids and subsequent harms from illegal drugs such as heroin and illicit fentanyl.

And the fifth point, the plaintiffs' evidence supporting their requested abatement remedy is entirely flawed and cannot support their claim for relief.

We said in our opening, Your Honor, that our case does not turn on denying the existence of an opioid epidemic, and it does not, but the record establishes that the plaintiffs have failed to prove their case in terms of causation, the existence of a public nuisance, and remedy. The case law, therefore, forecloses their claim.

So, let me now turn to some of these issues in more detail and I want to start with proximate causation. The requirement of a direct causal relationship between the alleged wrongdoing and the claimed harm.

Mr. Farrell's verdict form that he discussed yesterday never addressed this critical linkage between the defendants' conduct and the claimed injury and, in particular, the evidence reflects that proximate causation is defeated here by the prescribing decisions of doctors and the multiple criminal acts involved in diversion of opioids after they're prescribed.

This is not a question of pointing blame at others.

It's not a question of pointing fingers at others. It's rather a fundamental legal bar to the plaintiffs' claim.

The plaintiffs stake their case on the volume of prescription opioids that distributors shipped into Cabell-Huntington. The Court heard about this yesterday in Mr. Farrell's closing, 81 million pills, and they want the Court to conclude that the volume of shipments standing alone are sufficient to hold defendants liable for the entire opioid crisis in Cabell-Huntington.

But Mr. Farrell went 90 minutes into his closing before mentioning doctors and Ms. Kearse never even mentioned the central role of doctors in prescribing these medicines.

Now, the Court has already heard some of this before in the other two closings. Not surprisingly, because these are central issues in the case, but I want to build these building blocks of the legal conclusions by pointing to some of these critical facts that frame up the legal conclusion.

First of all, the evidence is conclusive and undisputed that prescribing by doctors and other medical professionals drove the volume of pills sold in Cabell-Huntington.

Dr. Gupta made the point very clearly in his opioid response plan. He said a critical factor fueling the national opioid epidemic is the rapid rise in opioid prescriptions. And he noted that West Virginia has experienced some of the highest rates of opioid prescribing

in the nation.

Dr. Keyes said that the high volume of opioid prescriptions that doctors were writing became the foundation for the overall expansion of opioid supply.

And Mr. Rafalski agreed when he was asked, there was no other way for his charts to increase, no other way for that hill to go up, for that hill to climb, without prescriptions.

So, if the volume of prescription opioids was excessive as the plaintiffs claim, this was the result of medical judgments made by doctors and changes in the standard of care, not actions taken by distributors.

Dr. Gupta made the point very clearly. He said you'd easily write several more days of prescriptions than you would require. He referred to a culture of attempting to reduce pain from a scale of whatever to zero for every West Virginian and he said that was the culture. That was the education. That was the influence. That was their understanding.

Distributors responded to what doctors were prescribing, but they did not decide the quantity of prescription pills. That was decided by doctors based on medical judgment.

Dr. Murphy, the University of Chicago economist, made the point very clearly. He said the amount that doctors

distribute -- the amount that distributors distribute is determined by the prescribing behavior and he said it's the prescribing behavior that determines the amount.

And this responds to the point that the Court asked about previously. Could supply drive demand? Not in this industry. Not in this industry where prescriptions are needed in order for any pills to leave a pharmacy. Clearly, as Dr. Murphy said, demand by the doctors working together with patients is what drove the level of volume.

Mr. Rannazzisi made this point very, very clearly. He said, no, supply is not what drives demand. Supply is not what drives demand. That's one of the plaintiffs' own experts.

And there was discussion previously today of the calculations by Ms. Lacey Keller, who determined that the average number of pills prescribed per person in Cabell County from 2006 to 2014 were 141.2 pills per person.

Looking at the shipment data from Dr. McCann based on ARCOS the shipment data showed 142 pills per person. This is conclusive evidence on the point that distributors only shipped what doctors prescribed. There's no other explanation for this observation. Clearly, distributors were responding to the prescription behavior of doctors.

Now, the Court asked previously today how does one decide on the reasonableness of a level of prescriptions?

Well, the reason -- or the reasonableness of the level of shipments, it's set by the doctor prescribing. Doctors made the judgment as to how many pills were needed. Distributors were responding to those judgments. That determines the reasonableness in this marketplace.

The evidence is also conclusive that this prescribing of opioids was overwhelmingly in good faith and the Court has heard some of this already, but just to highlight it, the DEA concluded nearly every prescription issued for prescription opioids is for a, quote, "legitimate medical purpose". Mr. Rannazzisi and Mr. Rafalski both said that 99 percent of the doctors were prescribing legitimately and Dr. Keyes said the overwhelming majority of doctors prescribed in good faith.

Mayor Williams of the City of Huntington likewise -- likewise testified that the vast majority of doctors in Cabell County and Huntington thought they were prescribing opioids appropriately.

And, furthermore, Dr. Keyes testified that pill mill doctors do not explain in any significant way the expansion of opioid supply or harms.

Not a single witness in this case said the distributors had anything to do with doctors' prescribing decisions or with the changes in the standard of care that the Court has heard about. And the evidence is also conclusive and

overwhelming that distributors cannot second-guess these good faith prescribing decisions by doctors.

This was stated very clearly by Mr. Rafalski and Mr. Rannazzisi. Mr. Rafalski said the DEA does not expect distributors to second-guess prescribers and Mr. Rannazzisi said a distributor cannot make the determination if a controlled substance is medically necessary and he said we've never asked a distributor to do that.

So, in hindsight, Your Honor, many in the medical community now believe that doctors previously prescribed too many pills, but doctors were asking under the then prevailing standards of care as they evolved and the decisions were for the doctors to make, not distributors.

So, let's turn to the second point. We've just discussed this first causal gap in the plaintiffs' evidence based on doctor prescribing. That is a core causal gap.

But there's a second one, as well. A second causal gap is that the harms created by diversion are caused by multiple criminal acts after opioids are prescribed. The only evidence of diversion in this record is when unused prescription opioids were diverted by family, or friends, or were sold.

Again, Dr. Keyes made this point very clearly. Quote, "Pervasive over-prescribing resulted in unused prescribed opioid medications diverted for monetary value, bartered, or

for no cost."

Stated, as well, very clearly again in the paper that's in evidence by Dr. Compton, the Deputy Director of the National Institute on Drug Abuse, where he said as a result of these shifts in practice, referring to the shifts in practice in prescribing behavior, quote, "unused pills became increasingly available for diversion and misuse". Unused pills, a key point.

And the plaintiffs make their same point, make the same point, in their abatement brief that they filed just this past weekend. As the plaintiffs said, as the volume of drugs increase, drugs will be kept in patient's homes where they may be diverted. This is the heart of the plaintiffs' case that these unused prescription opioids led to harms as the pills were diverted from medical use.

Dr. Gupta again made the point very clearly. He said so instead of three days of prescription, you write for 30 days. That's a problem. And he said that was a common mistake in the medical profession.

So, in other words, doctors made good faith decisions to prescribe opioids, but they prescribed too many pills that were left over or not needed and then the unused pills were diverted out of the medicine cabinet out of homes and led to this pattern of abuse and addiction. All of this happens after the pills leave the pharmacy and are being

used or abused.

Dr. Keyes again said that when she was talking about exposure and supply, she was talking about opioids that are out in the community. That's the issue. They're out in the community. They've left the pharmacy. They've been dispensed. This is medicine cabinet diversion.

The pills have been prescribed by a doctor, dispensed by a pharmacy, and they're out in the community, and they're being diverted after the pills left the Closed System of Distribution, after they left the closed system.

There is no evidence in this record of pills leaving the pharmacy shelf without a prescription and the evidence confirms that distributors have no control over what happens to pills once they leave the pharmacy.

Mr. Rannazzisi -- I'm sorry. Mr. Rafalski said it very clearly. Distributors have no control over what happens at that point after the pills leave the pharmacy and, in particular, there's no way a distributor could control how many days of pills a doctor decides to write for a particular prescription.

Recall what Dr. Gupta said. They were writing for 30 days when only three were needed. The distributor couldn't possibly control for that, but that's the major source of the unused pills that were then diverted. Or a doctor's decision in the first place that a prescription

opioid is the appropriate treatment for a patient in pain. Distributors don't control that.

So, in other words, what we're seeing is diversion that occurs when distributors do their job exactly as they're supposed to. The doctor prescribes the pills and then the patient sells, or gives them away, or the patient misuses the pills after they're prescribed.

Mr. Rannazzisi said this very clearly. He agreed the distributor does what they're supposed to do. The distributor does what they're supposed to do and the pills get sold, stolen, or given away.

So, medicine cabinet diversion is not something distributors create and it's not something they control. Medicine cabinet diversion involves intervening criminal conduct of the people who divert the pills to illicit uses and the people who illicitly use those pills without a prescription. This all happens outside the closed system after the prescription opioids leave the pharmacy.

So, let's put these two points together. Given the undisputed and overwhelming evidence that prescribing behavior drove the volume and given the undisputed and overwhelming evidence that medicine cabinet diversion is what caused the alleged harm, plaintiffs cannot establish proximate causation.

The guiding legal standard is found in *City of*

Charleston and *Employer Teamsters*, two cases from this district dismissing tort claims under West Virginia law for lack of proximate causation. As reflected in the quotations on the slide here, those decisions establish that there must be a direct relation between the claimed harm and the wrongful conduct. Both cases said the same thing, the necessity of distinguishing the direct consequences in a closed causal chain.

And, in particular, both decisions highlighted that doctors intervening and prescribing decisions and medical judgments defeated proximate causation under West Virginia law. And I want to highlight in particular this language from both of these cases, *City of Charleston* saying, "No injury would occur unless the physician proceeded to unnecessarily prescribe opioid treatments." That's Dr. Gupta's point, prescribing 30 days when three days were warranted.

And then *Employer Teamsters* which referred to the vast array of intervening events including, quote, "the independent medical judgment of doctors".

This record presents exactly the same issue, exactly the same issue. Dr. Keyes made the point explicitly. She said that without doctor prescribing there would be no opioid crisis. There would be no harm. She said her view is the opioid crisis would not have occurred if prescribing

opioids had not become standard practice. Would not have occurred.

City of Charleston found there could not be proximate causation where, quote, "no injury would have occurred", that's a quote from the case, without a doctor's prescription and that's exactly what Dr. Keyes says in this statement that's in the slide here. Her testimony fits precisely within the test established by *City of Charleston*.

Both decisions, both *City of Charleston* and *Employer Teamsters*, also highlighted other intervening acts, including, in particular, criminal conduct that defeated proximate causation. Both cases referred to many intervening causes. *City of Charleston* referred to including criminal actions of third parties.

Again, this record presents exactly the same issue. Exactly. There would be no harm without medicine cabinet diversion, as we've discussed, which involves multiple criminal acts after the pills are prescribed and dispensed. Diversion by family, friends, drug dealers, misuse, or subsequent illegal drug use.

These acts of diversion are crimes and these multiple criminal acts likewise defeat proximate causation under *City of Charleston* and *Employer Teamsters*. These cases set it out very clearly. It's the precise same issue.

Now, Mr. Majestro said yesterday that *City of*

Charleston distinguished distributors from the defendants in that case. And the defendant in that case, as the Court will recall, was the Joint Commission, which is the accrediting organization that developed the concept of pain as the fifth vital sign. We've heard a lot about that through nine or ten weeks of evidence.

But all Judge Copenhaver said is that the Joint Commission was even further removed in the causal change than distributors. He did not hold or suggest that proximate causation exists as to distributors. That wasn't the issue that was before him. He concluded that the Joint Commission was further removed.

But the same independent actors, the same independent actors whose intervening conduct defeated a showing of proximate causation in the *City of Charleston;* namely, doctors and criminal actors, also defeat proximate causation here. If anything, the Joint Commission had a far more direct role than distributors in prescribing behavior because, of course, the Joint Commission drove the development of pain as the fifth vital sign.

The Court's heard extensive evidence on how important that was in expanding the use of prescription opioids to treat pain and distributors had nothing to do with that. Yet, Judge Copenhaver said that was not enough to establish proximate causation.

It also bears emphasis that *City of Charleston* was decided on a motion to dismiss. This Court now has the benefit of a full record that demonstrates the absence of proximate causation on the record that I've just summarized for the Court.

Now, the plaintiffs have said in multiple briefs in this case that proximate causation depends solely on foreseeability, but that is not West Virginia law. Remoteness is clearly a component, a component of proximate causation, under West Virginia law. Foreseeability is also a component. They're both elements of the test of proximate causation.

And we see that very clearly in the *City of Charleston* case which referred both to foreseeability and remoteness at different passages in that opinion. As the Court assessed proximate causation, the Court looked at foreseeability. It then evaluated remoteness. Both elements had to be evaluated under West Virginia law.

And it bears emphasis that *City of Charleston* and *Employer Teamsters* apply this remoteness standard to reject West Virginia tort claims. The plaintiffs have suggested that these cases are not applying West Virginia law, but that's just wrong. They're applying the remoteness standard found in West Virginia law and citing to West Virginia state cases for that authority.

So, here, we have too many independent third-party actors standing between the distributors' conduct and the alleged harm. Doctor prescribing, that by itself is enough to defeat proximate causation, but we also have multiple criminal acts thereafter involved in this medicine cabinet diversion.

Now, plaintiffs have also blurred this issue of causation by suggesting that joint and several liability saves them on the issue of proximate causation, somehow that that avoids the problem they face, but that's wrong for two reasons.

First of all, joint and several liability does not apply here. The Court has previously held that the West Virginia apportionment statute does not apply, but that's not a holding that liability is joint and several.

And I put up on this slide the *Farley* case, a 1920 West Virginia Supreme Court case that's been cited on a number of occasions more recently, and the *Farley* case states the general rule, that tortfeasors acting independently are not jointly liable.

And it's notable to look at the facts of *Farley*. *Farley* involved the pollution of a stream by multiple coal companies and the West Virginia Supreme Court held that because those coal companies were acting separately and independently, they were not jointly liable even though

their alleged wrongful acts were quite similar and caused similar injury. In other words, all of the coal companies were putting residue, coal residue, into the same stream at around the same time but, nonetheless, because they were acting independently, joint and several liability does not apply, did not apply.

But even assuming that there's joint and several liability, that does not answer the requirement to show proximate causation. It's a separate question from joint and several liability and, as we've just discussed, proximate causation defeats the plaintiffs' claims under the holdings and the reasoning of *City of Charleston* and *Employer Teamsters*.

These two cases of this district set the framework. They answer the same legal issue. They address the same proximate causation issue now before the Court.

THE COURT: Do you know what the subsequent history of either one of those cases was?

MR. HESTER: On *Employer Teamsters* and *City of Charleston*, Your Honor?

THE COURT: Yes.

MR. HESTER: So, as I understand it, *City of Charleston*, there is a motion to amend the pleadings that's been pending for over a year, I believe, and in *Employer Teamsters*, I believe there was no appeal.

THE COURT: Okay.

MR. HESTER: So, given this overwhelming evidence that shipments were in response to doctors' prescribing decisions, the plaintiffs cannot establish a public nuisance and I want to underscore that. They cannot establish a public nuisance on this record.

And the record evidence establishes that the FDA approved prescription opioids for the treatment of pain with specific labeling warnings that highlighted both the risks and the benefits of these medicines.

And the Court will recall the testimony of Dr. Gilligan, who talked about black box warnings, noting that that was important where the FDA saw a serious specific risk that it wanted to cull out for doctors. That's what the FDA did. They identified risks and benefits for doctors and approved these drugs.

We also have the clear evidence that the DEA continually approved and expanded the quotas for these medicines based on its assessment in consultation with the FDA of the legitimate medical needs of the United States.

And that's a very important point again, the DEA making the judgment that the volume of prescription opioids in this country should properly increase in order to meet the medical needs of the United States and it did so in consultation with the FDA.

Mr. Farrell said yesterday that a volume of pills could be per se unreasonable. That cannot be right. The DEA sets quotas. The DEA permits the production and shipment of this volume of pills. It cannot possibly be correct to call that volume of pills per se unreasonable when the DEA, the agency charged with the responsibility, has decided that this volume of pills is necessary to meet the legitimate medical needs of the United States.

We've also heard quite a bit about the national medical community that urged much greater attention to the importance of treating pain over a 20-year period or more and also urged much greater use of prescription opioids.

We've also heard extensive testimony and discussion over the last two days about these standards issued by the West Virginia Board of Medicine; again, highlighting that doctors should be more attentive to treating pain and should be using prescription opioids to treat pain. This explicit encouragement from the West Virginia Board of Medicine is extremely important when we're talking about prescribing practices in West Virginia.

And we've quoted on this slide the testimony from Dr. Gupta who said, quote, "A doctor practicing in West Virginia should seek to follow the guidelines and policy statements that are issued by the Board of Medicine." So, here we have it, the Board of Medicine encouraging the use of opioids and

Dr. Gupta saying doctors are expected to adhere to that guidance.

So, when we put these points together we have the medical community and the key regulators, doctors, the Board of Medicine, FDA, DEA, the Joint Commission that accredits healthcare facilities, and others, they authorized, they directed, they encouraged the use of these medicines for treating pain.

And even today, even after all this attention that's been given to prescription opioids over the last decade or more, opioids continue to be recommended and approved and they're extensively prescribed even today for treating pain.

So, given the uncontroverted evidence of these judgments by doctors, the medical community, and key regulators, the record forecloses a public nuisance claim against distributors for supplying the medicines that doctors prescribed.

Under West Virginia law conduct which the public convenience imperatively demands cannot be a public nuisance. That's the *Pope v. Edward M. Rude* case.

Put another way, under the Restatement formulation of a public nuisance the distribution of a medicine to support the medical needs of patients as determined by doctor prescribing cannot be deemed an unreasonable interference with a right common to the public.

So, under either formulation we submit that this conduct cannot meet the standards for public nuisance. Distribution of these medicines is a critical service needed to support the medical judgments of doctors and to provide pain medicine to their patients.

Mr. Rannazzisi made this important point very clearly. He said he agreed that it's, quote, "vital that an adequate and uninterrupted supply of pharmaceutical controlled substances be available for effective patient care", a very important statement that bears directly on this question of a public nuisance.

We've already discussed the evidence that the overwhelming majority of prescriptions were written in good faith and that distributors only shipped what doctors prescribed. So, it follows that the overwhelming majority of shipments were necessary, were necessary, to respond to the good faith prescribing decisions of doctors.

Now, let's look at it the other way around. The implication that distributors of medical products should not distribute medicines that doctors are prescribing has profound and very risky implications. It cannot be what public nuisance law is intended to do. It would force distributors to second-guess doctors' prescribing decisions and precisely what the evidence reflects they cannot do.

And, as Mr. Rannazzisi acknowledged, the public health

would be injured if distributors did not ship medicines that doctors prescribed. As he said, it's a public health concern when pharmacies cannot dispense legitimate pharmaceutical controlled substances.

The idea that this should be a public nuisance would turn the law of public nuisance upside down. It would preclude or penalize legitimate activity taken in response to legitimate medical judgments made in good faith under prevailing standards of care.

This same theory of public nuisance could apply to the Smithfield ham example that the Court raised during the Rule 52 arguments, a product with legitimate benefits and legitimate uses that also has adverse health effects. As the Court noted, ham contributes to obesity. At least some people say it does. And to public health problems.

But that is not a public nuisance claim because virtually all products have risks alongside the benefits and this is particularly true for medicines, which always have risks and benefits. That's what doctors weigh when they prescribe them. And that's what the regulators weigh when they approve and permit products, medicinal products, to be in the marketplace.

So, it was one thing for the plaintiffs to plead a claim of public nuisance. As the plaintiffs noted to the Court, many courts have denied motions to dismiss public

nuisance claims and we understand that at the motion to dismiss phase, but we now have a full evidentiary record, the first one in the country involving distributors of prescription opioids. And the record we've just discussed demonstrates why this cannot be a public nuisance.

Mr. Farrell said in the Rule 52 arguments that they brought this public nuisance case, quote, "rather than bringing 8,000 personal injury cases". That demonstrates precisely why this is not a proper public nuisance claim. It's an amalgamation of potential personal injury cases, each one of which would present its own unique factual pattern.

And there's already a well-developed body of product liability law that applies where individuals are injured or claim injury from a product. Public nuisance law does not fit this sort of claim.

And we see that reflected very clearly in the Third Restatement of Torts, which says that mass harms caused by dangerous products are better addressed through the law of product liability.

THE COURT: Could the plaintiffs have brought a class action on behalf of the -- of the 8,000 people who were involved here?

MR. HESTER: I would think so, Your Honor, subject to resolution of any class action issues around commonality

and the like, but one could imagine that there still would be a theory of common -- common injury or common factual and legal issues that would suffuse that kind of a class action, I would think. I haven't looked at it that carefully.

But I think the point, is we have -- it's effectively a products-related claim claiming injury and seeking treatment for the injuries from the use of opioids. It feels like a classic concept of a products liability claim.

THE COURT: I think about the asbestos cases and there were thousands of cases, but there were individual plaintiffs, if I remember that correctly.

MR. HESTER: That's right, Your Honor, and that is the way those cases were resolved.

And as the Restatement says, quote, "The common law of public nuisance is an inept vehicle for these kinds of products claims."

And we see this stated very clearly in this *State v. Lead Industries* case, one of the -- one of the lead paint cases in a very thoughtful decision issued by the Rhode Island Supreme Court where the Court said, first, a public right is more than an aggregate of private rights by a large number of injured people. And the Court also said that the manufacture and distribution of products rarely, if ever, causes a violation of a public right that would support a public nuisance claim.

And this gets, Your Honor, to some of the cases that I think you just alluded to. Consistent with the reasoning that we've just discussed, a wide range of cases, from lead paint, to asbestos, to handguns, and many others, have recognized that public nuisance does not apply to what is essentially an amalgamation of personal injury claims.

And we've quoted some of the language here.

"Law of public nuisance never before has been applied to products, however harmful."

"Nuisance would become a monster that would devour in one gulp the entire law of tort."

"So broad and undefined that the presence of any potentially dangerous instrumentality could be deemed to threaten it" and so forth.

There are a lot of cases that follow this same line of reasoning and that have recognized the inherent problems presented when we are talking about applying public nuisance to products.

The Smithfield ham example was a good one. I think medical products are even better. Because they're prescribed by doctors to meet a medical need, there's an intervening judgment that these are important for a medical purpose and that's -- should, in my view, be the paradigm of a case that doesn't extend to product -- to a nuisance theory.

Of course, any medicine, any prescription medicine, has risks and benefits, but when doctors weigh the risks and benefits and prescribe a medicine in good faith to treat pain, the record demonstrates why it is vital that patients have access to that medicine because the implication of a nuisance theory here would be patients would have less access to medicine that doctors are prescribing to treat pain.

And the record demonstrates why it would be dangerous and, in fact, entirely unworkable to suggest that distributors should be placed in the position of second-guessing the medical judgments of doctors by refusing to ship what doctors are prescribing.

So, that gets us through public nuisance. Let's turn now to discuss the evidence of McKesson's distributions in Cabell-Huntington.

This exposes another fundamental gap in the plaintiffs' case against McKesson. They have no evidence of diversion by any of McKesson's customers in Cabell-Huntington. They have no evidence of any improper activity by any of McKesson's customers in Cabell-Huntington. They have no evidence that any of McKesson's shipments into Cabell-Huntington were improper or unlawful. And they have no evidence that any of McKesson's shipments into Cabell-Huntington caused harm.

Now, the plaintiffs repeatedly mentioned 81 million pills yesterday in their closings, but McKesson did not distribute 81 million pills in Cabell-Huntington. In fact, if we look at the data, 76 percent of McKesson's distributions in Cabell-Huntington went to the VA Hospital.

And the plaintiffs do not contest those shipments to the VA. In fact, they don't allege that the VA shipments were excessive. They excluded the VA shipments from their analysis. They presented no evidence of diversion from the VA shipments. No evidence of any harm from the VA shipments.

THE COURT: But there wasn't anything about the VA situation that made the possibility for diversion there much different than non-VA pills, was there?

MR. HESTER: Well, it's -- the record is entirely silent on it, Your Honor, and the plaintiffs certainly presented no evidence of any diversion from VA shipments.

And the point I wanted to highlight here in particular, two of the plaintiffs' experts explained they were not looking at the VA. So, Mr. -- Dr. McCann excluded the VA summaries from his analysis.

But then, if you look at Mr. Rafalski's statement on the right-hand side, he said the diversion is occurring at the retail pharmacy level. And so, it wouldn't have been, as he said, prudent to include a hospital in the analysis.

So, Mr. Rafalski almost pointed it the other way, Your Honor, saying that he didn't think it was appropriate to look at the VA shipments in evaluating diversion but, certainly, the plaintiffs presented no evidence at all, made no --

THE COURT: I'm puzzled by this. It seems like, you know, you go into the hospital and you have surgery and they give you a bottle of pills to take home with you. I don't see that as any different than picking them up at the pharmacy.

MR. HESTER: Well, I think our point, Your Honor, is principally an entire lack of evidence and the plaintiffs -- the plaintiffs, in fact, excluded the VA entirely from their own analysis when they present a theory of diversion.

But putting aside the VA shipments, McKesson is only the sixth largest distributor of prescription opioids into Cabell-Huntington.

And putting aside the VA, McKesson shipped 5.5 million pills into Cabell-Huntington from 2006 to 2014.

So, I have put up a slide here from Mr. -- Dr. McCann. He said there were 36 distributors of prescription opioids in Cabell-Huntington over this period. There were five companies that shipped more than McKesson. That amounted to close to 200 million MMEs of pills. And, as he said, that's not a dominicus amount. So, in other words, there's a lot

of others that were distributing in Cabell-Huntington.

And so, McKesson's share if you remove the VA amounts to six percent of the volume of shipments into Cabell-Huntington putting aside the VA. And if the plaintiffs' entire theory is high volume it doesn't hold water as to McKesson.

Now, plaintiffs blur this point by pointing to McKesson shipments outside of Cabell-Huntington. Their directed verdict briefing names nine pharmacies served by McKesson that are between 50 and 150 miles outside of Cabell County and the red dots on this slide reflect it, quite a long way away, and they just pointed to two pharmacies in Cabell-Huntington in their briefing that were customers of McKesson, I should say.

And as Dr. McCann testified, there is no evidence that any patients from Huntington or Cabell ever visited any of the nine pharmacies outside of Cabell-Huntington that the plaintiffs had identified and we've quoted that on the slide. He did not identify any patients who went to any of those pharmacies from Cabell-Huntington.

The plaintiffs also go even further outside Huntington and Cabell to internet pharmacies that were operating in Florida, but the evidence of diversion and drug trafficking related to internet pharmacies is completely stale. Congress barred internet pharmacies in 2008. It's not been

happening for over a dozen years, as Mr. Rannazzisi acknowledged.

And even as to the internet pharmacies operating prior to 2008, there's no evidence that any distributor in this case ever shipped to any internet pharmacy whose pills made their way to Huntington or Cabell. There is just no evidence on this at all that links these internet pharmacies to Huntington-Cabell, but perhaps the more important point of all is it's more than a dozen years old and we're in a forward-looking case.

So, in short, there's no evidence that links McKesson shipments to these other pharmacies to any harms in Cabell-Huntington and McKesson's small share in Cabell-Huntington defeats causation. These small shipments cannot have been a substantial factor in plaintiffs' claim that excessive volumes of opioids caused them harm.

The claims cannot properly rely on this talisman of 81 million pills as their core theory of liability without grappling with the fact that McKesson had only a very, very small share of that volume. They can't have both sides of this.

And McKesson, in fact, had only a few customers in Cabell-Huntington and none were even mentioned in the plaintiffs' closing. As Mr. Ashworth, the sales rep who serves Cabell-Huntington said, currently has three customers

in Cabell-Huntington and he had a couple of customers if he went back to 2010. And the plaintiffs have no evidence of any wrongdoing in McKesson's sales to these customers or any misconduct by its customers.

Mr. Rafalski said he was not offering any opinions about whether diversion occurred at a pharmacy level in Cabell-Huntington.

And Mr. Rannazzisi said he could not identify any orders that he believes DEA should have blocked in Cabell-Huntington but were not.

The only -- and to the contrary -- so there's no evidence of misconduct and, to the contrary, the West Virginia Board of Pharmacy concluded that Rite Aid, one of McKesson's customers in Cabell-Huntington, dispenses medications only for legitimate medical purpose and is a, quote, "good pharmacy", in all caps, underlined, and with an exclamation point, the Board of Pharmacy reviewing Rite Aid, one of McKesson's customers, consistently finding it was complying with the law and was a good pharmacy.

The only other record evidence of a McKesson customer in Cabell-Huntington relates to Custom Script, which was the twenty-sixth largest pharmacy in the community, and served primarily oncology clinics and Hospice facilities.

Now, let's contrast that. Let's contrast the lack of evidence of any -- of any wrongdoing with the evidence of A+

Pharmacy.

The evidence reflects that Miami-Luken, a distributor that's not in this case, supplied A+ Pharmacy, a bad pharmacy that was shut down in Cabell-Huntington. A+ Pharmacy was never supplied by any of these defendants. A+ dispensed more than a half million prescription opioids and, in 2014 alone, this represented 97 percent of the pills seized by the Huntington Police Department.

Your Honor, if we wanted to find a case of actual pharmacy-level diversion, actual wrongdoing, this would be it. This is what it looks like. This is the kind of evidence that the Court might have been anticipating when the case began. Yet, Miami-Luken is not even a defendant in this case that alleges harm from the distribution of opioids.

So, as we've discussed, the plaintiffs' case is based on their claim that the volume of prescription opioids was excessive. That's the core. That's the heart of what they're claiming.

But the key players who contributed to this volume of prescription opioids are not parties here. Doctors who prescribed the volume of pills. Drug dealers who illegally trafficked prescription opioids into the community. Manufacturers who developed these prescription opioids and then promoted the prescribing of these pills to doctors.

Pharmacies that dispensed prescription opioids in Cabell-Huntington.

Three distributors, not defendants here, that accounted for a larger volume of prescription opioids in Cabell-Huntington than McKesson. And Miami-Luken, of course, which supplied A+ Pharmacy.

These are clear examples of missing parties that had a much more direct role in the volumes at stake here and the volumes that the plaintiffs relied upon, volumes that plaintiffs claim their harm.

So, to sum up, there is no record evidence to support a finding that McKesson was a substantial factor in causing the opioid crisis in Cabell-Huntington, particularly where, unlike Miami-Luken, there's no evidence of any issues with any of the pharmacies McKesson served.

So, Your Honor, let me turn to a new subject. The plaintiffs claim the distributors' failure to report suspicious orders proves causation, but they have no evidence linking suspicious order reporting to diversion or to any harms in Cabell-Huntington. The evidence, in fact, directly contradicts plaintiffs' theory that diversion was caused by the defendants' failure to report suspicious orders.

First of all, McKesson and the others always reported all shipments to the ARCOS database. These volumes were

known and fully available to the DEA. And they were public, always public, at the three-digit zip code level.

No federal or state regulator ever said that McKesson's shipments were excessive or inappropriate. No federal or state regulator ever said that McKesson's shipments were unreasonable.

The evidence also establishes that McKesson always blocked orders that were likely to be diverted. It was very clear it was done before 2008 and after 2008. Orders likely to be diverted were always blocked. And it's important to emphasize that orders likely to be diverted are different from suspicious orders.

I'm sure the Court has struggled a bit with the language of this regulation, the classically vague regulatory formulation defining a suspicious order as an order of unusual size or frequency or deviating from a normal pattern.

The record establishes that there are many benign, completely neutral reasons that an order might vary in size or frequency. Mr. Rafalski said there were all kinds of circumstances where an order can be of unusual size, pattern or frequency and not be diverted. He agreed with that statement.

Now, before 2008, based on DEA's guidance and industry practice, McKesson reported all suspicious orders, but only

blocked the orders that it believed were likely to be diverted.

Mr. Rannazzisi testified that no distributor, no distributor, was blocking all suspicious orders before 2008. And we see this reflected clearly in the money case, *United States v. $463,000-and-some* out of the Eastern District of Michigan where the Court said that it was a standard practice to file Suspicious Order Reports while continuing to ship products and further said that practice had been approved by the DEA. This was based on testimony of DEA witnesses. And there was also testimony in that case that DEA changed its policies around 2006 or '7.

We see the same point in the *Masters Pharmaceutical* decision from the D. C. Circuit which similarly reflects that the requirement not to ship suspicious orders was first articulated in the *Southwood* decision, which was in 2007.

So, we see starting in 2008 McKesson blocked all suspicious orders, but it reported less. That was based on specific guidance from DEA that it wanted fewer Suspicious Order Reports, and it -- but it did want distributors to block all suspicious orders.

Now, in 2008, McKesson reached a settlement agreement with DEA that involved no admission of wrongdoing and, in response, the DEA reviewed and passed McKesson's Suspicious Order Monitoring Program. McKesson told DEA that it would

be reporting fewer suspicious orders as DEA had requested. DEA passed and raised no objection to that practice.

In 2017, McKesson entered into a second Settlement Agreement with DEA. This related to suspicious order reporting before 2013 because McKesson changed its reporting immediately after this issue first arose in 2013. The only admission, the only admission in that Settlement Agreement, related to whether McKesson had sufficiently reported those suspicious orders.

The 2017 settlement had no admission of any failure to block. There's a very important distinction between reporting and blocking. There was no admission of any failure to block suspicious orders and there was no admission of any diversion or any lack of sufficient due diligence on customers or orders.

So, this second settlement reflected DEA's changing guidance on the reporting of suspicious orders that it wanted more. There was a period of time when it wanted less. It then wanted more. That was based -- that was reflected in this settlement.

But, notably, the evidence also reflects that DEA did nothing with these Suspicious Order Reports even when they were received. There was no action taken on any suspicious orders.

Mr. Rafalski acknowledged that he couldn't point to any

action that DEA took on any suspicious order that McKesson, Cardinal or ABDC made for Cabell County or Huntington.

Mr. Rannazzisi couldn't even say whether more than one percent of suspicious orders had triggered an investigation by DEA.

And, in fact, we see a recent Office of Inspector General Report that's in the record that found an utter failure by DEA to take any action in response to this suspicious order reporting. One finding was that the suspicious order reporting database was seen within DEA as a, quote, "joke" and that Field Division staff did not even have access to this suspicious order reporting database until 2017.

Another finding was that when they asked the Field Division staff to find Suspicious Order Reports, they couldn't even locate them.

So, this evidence reflects that it would not have mattered if more suspicious orders had been reported. DEA was doing nothing with them even when they were reported.

Perhaps even more important, Your Honor, for purposes of this forward-looking case, there is no evidence of any failures to report suspicious orders after 2013. So, here we are in 2021 in a case that seeks a forward-looking remedy over 15 years and the evidence establishes, first, that all orders likely to be diverted have always been blocked. All

orders likely to be diverted have always been blocked. And the evidence establishes that all suspicious orders have been blocked since at least 2008; so, for more than a dozen years.

There cannot be any harm or any diversion from orders that were blocked and not shipped. Mr. Rannazzisi acknowledged this. He agreed if the order is blocked the medicine can't go downstream. It makes sense. If it's blocked it can't get out to the public. It can't be diverted.

Mr. Rafalski said the same thing. He agreed, if you block an order, it would not lead to diversion. He said blocking the order -- he agreed, blocking the order is what prevents diversion.

Now, Mr. Rafalski did suggest that more orders should have been flagged and he came up with his own methodology for flagging more suspicious orders. And there's been quite a bit of briefing to the Court on this. I'll go through it quickly.

The important point is his testimony cannot be credited. He used a methodology that was never used at the DEA to identify suspicious orders and was created solely for purposes of litigation. He presented six methods for detecting suspicious orders, but on the witness stand he disclaimed four of them as not plausible.

He had no opinion about how many flagged orders should have been reported to DEA. He did not evaluate the medical needs related to any harm from flagged orders.

He had a remarkably wide range of error, from 20 percent in one analysis to 97 percent in another, shocking imprecision in methodology and his analysis was incompatible with DEA's own estimate of only .1 percent of orders being suspicious and diverted.

So -- and he also applied -- he applied his no-due-diligence assumption without reviewing any orders and I want to go back to that point in a little more detail.

What happened with Mr. Rafalski's methodology was a highly artificial flagging of orders. If the threshold was exceeded in one month, his method assumed that all subsequent orders were suspicious even if none exceeded the threshold after that first month.

And the Court will recall these two charts, the one on the left reflecting his assumption that every order after a first month should have been flagged as suspicious when, in fact, only one month's order exceeded the threshold, as reflected in the right-hand side of this slide.

Mr. Rafalski based his methodology on an assumption that no diligence was conducted on suspicious orders. That was an assumption he did not check and it was contradicted by the record. The record establishes that McKesson and

others systematically conducted diligence on blocked orders. And Mr. Rafalski said in response to that point he couldn't find evidence of this diligence a decade later when he did his analysis.

But the evidence established that there was no requirement to keep diligence records for a decade or more. Generally speaking, the records retention was two years for these diligence files, as reflected in the testimony of Mr. Oriente and others. So, the fact that Mr. Rafalski couldn't find diligence files a decade later is not proof that the diligence was not done and, to the contrary, the direct evidence from those who were involved is that diligence was done. It was conducted for both customers and orders. And this evidence directly undermines the core premise and the core assumption of Mr. Rafalski's flagging methodology.

Furthermore, even if Mr. Rafalski is right that more orders should have been flagged as suspicious, an order, whether it is suspicious or not, would sit on the shelf harming no one unless a doctor writes a prescription and the pills are dispensed.

And this is the point that Dr. Gupta made, Dr. Keyes made. They both agree pills don't leave the pharmacy without a prescription. I think we've established that clearly in this record.

And this shows why the plaintiffs' theory of harm is

not based on suspicious order monitoring or reporting and I want to underscore that. Their theory of harm is not based on suspicious order reporting.

Their theory of harm depends on prescriptions being written. The only harm that occurs is when doctors write prescriptions and the pills are dispensed and out in the community.

The question of whether more orders should have been reported doesn't bear on the question of whether, in fact, the pills get out into the community. That is caused by doctor prescribing. This is made very clear in the testimony of Mr. Rafalski, who agreed that not reporting suspicious orders to DEA is not what causes diversion.

It also bears emphasis that the State of West Virginia has repeatedly licensed McKesson to distribute prescription opioids. That reflects the State's own finding that McKesson is operating in compliance with federal legal requirements and is maintaining effective controls against diversion. That's the basis for the State of West Virginia's authorizations.

And based on these determinations, the State of West Virginia has approved McKesson 150 times since 2014 alone and I would submit that ties back, Your Honor, to the public nuisance point we discussed a bit ago. The State needs these distributors to operate, to provide medicines that

doctors are prescribing.

The Court need not resolve every detail of these suspicious order reporting issues to conclude that they're irrelevant to plaintiffs' claimed harm. Failures to report some suspicious orders, even if they happened, could not have contributed to excessive volume and could not have caused harm because the record establishes these orders were blocked and never shipped. Whether they were reported or not, they were blocked.

And I want to highlight again the harm that the plaintiffs claim in this case is from the volume of pills dispensed by pharmacies that went into medicine cabinets and ended up being misused, abused, or given away. That harm could not have occurred from orders that were blocked and never shipped. Whether or not more should have been reported to DEA as suspicious, the point is, they were blocked. They didn't contribute to the volume that the plaintiffs claim caused them harm.

I'm ready to turn to a new subject, Your Honor. Should we keep going?

THE COURT: Yeah. I think we probably need a break here, Mr. Hester.

MR. HESTER: All right, Your Honor.

THE COURT: We will be in recess for ten minutes.

(Recess taken)

THE COURT: You may proceed, Mr. Hester.

MR. HESTER: Thank you for the short break, Your Honor.

Before I move on to my next topic, I did want to go back to one point. I don't want to oversell the idea of class actions for products cases. I don't want to -- I don't want to overstate the prospects for that.

I do think, perhaps as this litigation reflects, there are ways to consolidate litigation through Bellwethers and other mechanisms probably, in fairness, class actions involving straight products liability claims have not been certified so far as we know. So, I checked with my brethren, who know more about this than I do, but I just didn't want to oversell to the Court that that was an easy alternative.

I think it's probably complicated, but I think our real point is it's not a public nuisance and there would be consolidated frameworks by which that kind of litigation could be handled, as we're seeing in this case.

So, let me turn along to my next subject, which is illegal drug abuse. I'm going to turn to what we see as a different gap in the plaintiffs' evidence of causation related to illegal drug abuse.

The evidence shows a 50 percent decline in opioid prescribing since 2013. The volume of prescription opioids

on which plaintiffs stake their case has declined dramatically.

The Pill Mountain that Mr. Farrell highlighted in his opening has really disappeared or fallen away. And the recent volumes that we see with prescribing are vastly lower than Mr. Farrell's 81 million pills between 2006 and 2014. If we moved it forward, we would see lower volumes.

And it's reflected here in the testimony from Dr. Gupta, who said there's been a quite significant decline, 52 percent decline in prescribing between 2014 and 2019.

So, any crisis created by the volume of prescription opioids ended years ago. That's a highly significant point in a case involving solely prospective relief. Plaintiffs have no evidence that today's level, today's level of opioid prescribing, is excessive and they focused almost entirely -- when they talk about prescription opioid shipments, prescription opioid volumes, they're almost always relying on evidence that's at least a decade old.

And there's been a lot of discussion in this case of evidence as far back as 2007-2008 related to prescription opioid volumes. That has changed fundamentally.

So, the record establishes, in fact, that this is no longer a prescription opioid crisis. It has shifted. As Dr. Gilligan said, it has shifted to the abuse and misuse of heroin and fentanyl and fentanyl analogues. It's a crisis

of heroin and fentanyl abuse.

Sheriff Zerkle said the same thing. Pills were very prominent in 2007 to 2010. As of 2017, he said the issue, predominantly heroin. He said now most of our Drug Unit stuff is more toward the meth side now.

Mr. Lemley stated that the community had, quote, "moved on from prescription opioids", progressed to heroin and fentanyl and carfentanil.

And Dr. Smith's charts reflected the point and illustrated the point very clearly that the issue in Cabell-Huntington today is overdoses from heroin and illicit fentanyl and we see this enormous spike in fentanyl overdoses starting around 2014 and moving forward.

So, the plaintiffs pivot. With the huge drop in prescribing they pivot to blame distributors for this illegal drug crisis, but there are several fundamental flaws in the illegal drug theory.

First of all, this cannot possibly meet the proximate causation requirements. The plaintiffs' theory is that the volume of prescription opioids led to later abuse of illegal drugs, but as the Court is well aware and the record reflects, illegal drugs are driven by drug cartels and drug dealers, not the distributors of lawful medicines.

Very colorfully stated by Sheriff Zerkle, who talked about when we arrest someone, there's someone in Detroit

saying saddle your horse. You're going to Huntington. The police documents noting that Huntington has often been referred to as Little Detroit.

Mayor Williams emphasized that Detroit drug dealers are a significant cause of the opioid problem and he said Detroit and other cities, yes.

And, of course, illegal actors took extensive action to increase the market for heroin and illicit fentanyl. Dr. Gupta described they reduced the price of heroin. They increased the purity of heroin to unseen levels, more pure, lower price. They increased the supply of heroin.

And, as reflected in the report from Dr. Compton of the National Institute on Drug Abuse, they sold heroin like pizza, a pizza delivery-like way of marketing heroin to potential suburban buyers who otherwise might have been frightened to engage with the illicit drug trade. That's what's happened in recent years.

And, of course, licensed pharmaceutical distributors had nothing to do with these decisions and with these actions taken entirely by criminal actors. So, this criminal activity is a fundamental obstacle to the plaintiffs' theory based on illegal drug use.

There was a nice discussion by Mr. -- Ms. Mainigi this morning of the sequence. We have prescription opioids stolen or given away, a crime. Prescription opioids being

misused for a non-medical purpose, a crime. A person who develops OUD as a consequence. A person with OUD who subsequently acquires illegal drugs, another crime. Drug traffickers or cartels who supply those illegal drugs, another crime.

Now, the plaintiffs are simply wrong in suggesting that illegal drugs are just, quote, "the other side of the coin from prescription opioids", or that prescription opioids, there was a colorful phrase yesterday in the closings are, quote, "pharmaceutical grade heroin", kind of a shocking assertion, I think.

To the contrary, heroin abuse is the result of extensive criminal activity by Mexican drug cartels and other illegal criminal organizations. By drug dealers. By those who adulterate heroin with fentanyl. And by those who buy and abuse those illegal drugs. That is a far cry from a doctor prescribing an FDA approved medicine for the treatment of a legitimate medical need.

City of Charleston again tells us the answer and demonstrates that proximate causation cannot be established as to this illegal drug activity. Illegal drug use under the *City of Charleston* test is unduly remote. And we've put the language up here on the slide where plaintiffs claims rely on, quote, "various criminal actions by third parties". The Court found that these were too many intervening causes,

including the criminal actions of third parties.

That's the exact same issue presented here in relation to illegal drug use. It's already been decided by the *City of Charleston* decision.

Now, the plaintiffs try to bypass this issue of proximate causation by arguing it was foreseeable that prescription drug abuse would lead to later illegal drug use, but that's not a correct statement of West Virginia law, as we've previously discussed. Remoteness and foreseeability are both elements of proximate causation under West Virginia law, as *City of Charleston* itself reflects.

But even under the plaintiffs' foreseeability theory there's no evidence that these harms were foreseeable. There is no evidence that distributors should have foreseen and expected that illegal drug cartels from Mexico and elsewhere would flood the market with low price high purity heroin or would adulterate the heroin supply with illicit fentanyl.

There's no evidence that doctors prescribing medicine in good faith foresaw illegal drug use.

There's no evidence that DEA foresaw illegal drug use when it was continually increasing the quotas for prescription opioids.

There's no evidence that FDA foresaw illegal drug use

when it approved prescription opioids for the treatment of pain.

And there's no evidence that the West Virginia Board of Medicine foresaw illegal drug use when it encouraged doctors in West Virginia over and over again to be more attentive to patients' pain and to use more prescription opioids.

The illegal drug crisis cannot have been foreseeable to distributors when every aspect of the healthcare and regulatory system in this country encouraged increased prescribing without ever thinking it would lead to a heroin-fentanyl crisis.

So, in short, proximate causation is a complete answer to a claim of harms flowing from prescription opioids to subsequent illegal drug use. It fails on proximate causation grounds under *City of Charleston*.

But there's also a second complete answer to plaintiffs' illegal drug theory. Plaintiffs, of course, have asserted a direct causal gateway between prescription opioids and later illegal drug use. This does not stand up to the evidence.

Plaintiffs rest their gateway theory on the evidence that many heroin users previously abused prescription opioids, but the plaintiffs do not have evidence establishing that prior abuse of prescription opioids causes -- causes later heroin abuse.

Rather, the evidence reflects that what we're measuring here is a broader substance abuse problem, that heroin users who previously abused prescription opioids in fact abused many other drugs.

And the most powerful study on that is the one reflecting that 80 percent of heroin users had previously abused prescription opioids, something we've talked about with the Court quite a bit, but that same study also found that almost 100 percent of those heroin users had previously abused other illegal drugs, reflecting this point. It's a substance abuse problem. It's not a simple gateway, pills to heroin.

Dr. Keyes acknowledged that heroin users have broader substance abuse problems. She noted the most common first substance use is tobacco and alcohol. Then there's a progression to other drugs.

Dr. Gilligan described the same point, that it's a broader substance abuse problem that we're seeing.

And this was summed up nicely and effectively in the article from Dr. Compton, again, the Director -- Deputy Director of the National Institute on Drug Abuse, who said that "conclusions", quote, "about cause and effect between prescription opioid abuse and later heroin abuse is uncertain and that other factors explain this transition from one to the other, including changes in the heroin

supply and the heroin market."

So, in short, the supposed gateway, the theory that prescription opioid abuse causes, causes later heroin abuse, is not supported by the evidence. And the evidence of a gateway is surely too thin, too thin to hold distributors liable for the illegal drug activity of criminal actors in drug cartels.

But I want to emphasize the Court need not resolve this whole gateway issue to reject these illegal drug claims for failure to proximate causation. It's a much simpler way to get to the answer because *City of Charleston* tells us the answer. They can't establish proximate causation where they have all of these intervening acts of illegal actors in the drug chain for illegal drugs. We don't need to resolve the gateway to reach the conclusion under *City of Charleston*.

Let me turn to my last topic, Your Honor, the abatement remedy. In our Rule 52 motion and argument we already addressed the core legal and analytical flaws in the abatement remedy.

And just to summarize briefly, almost the entire remedy is for treatment and for harms related to opioid abuse. The remedy is not addressing the distributors' conduct but is instead seeking payment for the treatment of opioid use and addiction and related harms.

And in their closings yesterday, both Mr. Farrell and

Ms. Kearse highlighted that the plaintiffs are seeking money predominantly for treatment of addiction as the core element of their remedy. Yet, the plaintiffs waived any claim for damages, stated clearly in this slide on the board, and treatment costs are clearly damages arising from opioid addiction and abuse.

In addition, and even more fundamentally, abatement, the purpose of abatement, is to address conduct giving rise to a nuisance, not the downstream harms caused by the nuisance. Here the claimed nuisance, as the plaintiffs have articulated it, is the excessive distribution of the volume of opioids. Yet, the plaintiffs are not seeking any remedy that's realistically tied to the level of distributions or the volume of prescription opioids. They're instead seeking money for the harms caused by addiction and abuse.

Treatment of harms is not a proper abatement remedy. That is not addressing the conduct said to give rise to the nuisance.

Another flaw. A huge part of the plaintiffs' remedy is for future addiction for people who develop addiction years into the future. The Court will recall the question that was put to Dr. Alexander about a child who is ten years old as of 2021, has never used opioids, begins using opioids in -- or begins abusing heroin in 2027 as a teenager and develops OUD. That person who develops OUD years into the

future from heroin abuse would be included within the scope of the plaintiffs' remedy.

Yet, the plaintiffs have no evidence of any future conduct, future conduct by defendants, that could make them liable for this kind of future addiction. And, in fact, plaintiffs' abatement brief acknowledges this point. They say there will be new cases that are required to be abated, quote, "whether or not they are the direct result of defendants' conduct".

That's a fairly shocking concept, liability without causation. It's directly at odds with basic principles of tort law to suggest that new cases could be subject to abatement that these defendants have to pay for, whether or not the result of defendants' conduct.

The remedy also includes people who were never exposed to prescription opioids at all, another central flaw in causation, the suggestion that somehow a person who has never, ever been exposed to prescription opioids would be entitled to be included within the scope of this abatement remedy. Defendants cannot be held liable for harms to people who are never exposed to the products they distribute.

Another flaw. The remedy is clearly unreasonable. The City and the County do not administer or pay for these services and would receive vast amounts of money for

programs in which they play no role. So, today, the City and the County in total devote $136,000.00 to opioid-related projects and -- projects and programs. That's based on the testimony of Dr. Rufus. And the plaintiffs are claiming $2.5 billion dollars when they spend today $136,000.00 on opioid-related programs.

And as reflected in particular in the fact -- in the statement by the mayor, he said the City has never funded opioid treatment and he said I never would expect the city government to actually start running treatment programs. Yet, more than $2 billion dollars, more than $2 billion dollars of this remedy, is for treatment programs. So, the City would be receiving this vast amount of money for things it does not do.

And, in fact, as the Court has heard, almost everyone in West Virginia has health insurance which already covers these treatment costs and health insurance is not grant funding. It's health insurance that already pays for the treatment costs that make up the vast bulk of the plaintiffs' abatement plan and there's no record evidence that this health insurance funding is unstable or uncertain into the future and there's no evidence in this record that this funding that already exists is inadequate to provide ongoing funding for the treatment programs for people in Cabell-Huntington with addiction.

Now, plaintiffs have made the suggestion that it's no issue that they don't run or pay for these programs today because they want the Court to establish a, quote, "court supervised trust fund" to pay for the programs that the City and County do not fund or administer.

There is, first of all, no evidence in this record that third parties need additional funds to provide the programs to address the opioid crisis that they're already providing. There's no evidence in this record. It's silent on that issue. So, there is no evidence to support creating a fund for programs that have never shown a need for more funding.

For instance, funding is not needed to pay for treatment programs that Medicare and other insurance already pay for. And without evidence, there's no basis to establish this fund. There's no basis to establish a need for a fund to support programs that are already running without this funding.

But perhaps even more fundamentally, Your Honor, the idea of this Court-supervised trust fund is unmoored from tort law principles of causation. It would suggest the Court can create a fund that disburses money to parties that have made no showing of any injury caused by the defendants. There would be no mechanism by which that would happen. These parties are not here and they would be receiving money somehow out of this fund.

And the plaintiffs have also presented no evidence or explanation as to how the fund would be administered or overseen, who would be eligible for payments from the fund, what the criteria would be for determining payments from the fund, or what would happen with unused funds.

This is social policy. It's not a tort principle.

But let's put to one side the flaws of this fund proposal and the flaws that we already discussed in our Rule 52 motion. Let's look at the record evidence. The record evidence demonstrated that Dr. Alexander's model is unreliable and reflects a total failure of methodology.

First of all, the Court will recall the testimony of Dr. O'Connell about the Resiliency Plan. The Resiliency Plan was developed by the community to assess what sort of resources they needed as they looked ahead over a 40-year period, what would they need to become healthy, as Dr. O'Connell put it, and that Resiliency Plan directly contradicts Dr. Alexander's estimate, for instance, that the City and County need over $2 billion dollars in treatment money as we look ahead.

And recall that Dr. O'Connell said that the premise of this Resiliency Plan was to assume no budget, no limit, no constraint on the funding. What would you need? Assume no limits. And that's -- and that's what the community came up with.

So, let's look at what they did. They came up with a Resiliency Plan. The first draft had treatment costs of $23 million dollars. Unspecified duration.

The next version of the plan, treatment costs of $50 million dollars over 40 years. Again, assuming no limit on funding at all, that's the number that the community came up with when they assessed what they were doing and what they would need as they looked ahead.

That $50 million dollars continued through the August 22 draft. Continued into the September 3, 2019 draft, the last version that had numbers in it before those were stripped out.

Let's look at what the abatement plan number has. Instead of $50 million dollars over a 40-year window, which is what the community said it needed, the abatement plan shockingly comes up with a number for treatment of over $2 billion dollars over 15 years. It just utterly impeaches the credibility of this abatement plan.

And as reflected in what we see here, we see this huge divergence between the Resiliency Plan and Dr. Alexander's model. We can see that the individual cost projections in his model are completely inflated.

For an example, he comes up with a Syringe Services Program number and his Syringe Services Program number as calculated by Mr. Barrett was for a number of $12.6 million

dollars over a 15-year window and that would serve roughly 1,000 people.

Well, the plaintiffs had an expert, Dr. Feinberg, who testified that she had actually run a Syringe Services Program for $60,000.00 a year serving perhaps 1,400 or 1,500 people. Now, note Dr. Feinberg's number was an annual number. So, multiply it by 15. Still $900,000.00 compared to $12 million. It's just a shocking divergence from reality in what we see in the Alexander model.

We see another example. The treatment costs that Dr. Alexander estimated failed to take account of the actual duration of treatment that we see in the real world.

The TEDS data that was discussed during the trial is the data compiled by the federal government that reflects the actual duration of treatment and the TEDS data reflects that the actual duration of outpatient treatment on average is 71 days.

Well, Dr. Alexander assumed 365 days. And he had other categories of treatment where he similarly assumed very long outpatient programs that would be much, much longer than that 71-day number.

So, Dr. Rufus did the calculation. If we just made that one adjustment, 71 days instead of this unrealistic out-of-touch assumption that Dr. Alexander made, we would drop the treatment number in the Alexander plan by $1

billion dollars. The fact that one assumption changes the numbers by a billion dollars shows they are unreliable.

Now, the plaintiffs yesterday in their closing suggested that the defendants somehow had, quote, "agreed" that the proper treatment number, therefore, must be between $600 million and $1.7 billion, the Rufus number versus the Alexander number. I think they missed the point entirely.

We've already discussed why the plaintiffs are not entitled to recover anything for treatment. Treatment is for downstream harms caused by drug abuse. It's not properly abatement and the plaintiffs have waived any claim for damages.

But the key point is, it just reflects a flaw of methodology. That's the reason that we're highlighting this point. When numbers swing a billion dollars from making an assumption that simply reflects the reality of what's happening in this country it raises fundamental questions about the reliability of the model. There's also clearly an utter failure in the Alexander model to take any account of the community activity that's already underway.

Now, the plaintiffs in their paper that they filed over this past week said that the Alexander plan, quote, "takes into account that current programs are insufficient". That's simply not true and that's not what the evidence is in this record.

Dr. Young said that it was beyond the scope of her report to look at what is in Cabell County and she said there are other experts who were doing that, not her. Well, in fact, no expert for the plaintiffs did that.

Dr. Alexander said he didn't do it. He was asked did you subtract out the level of services that are currently being provided? No, I did not.

Mr. Barrett said he didn't do it either. He didn't take any account of the programs that are currently being offered in Cabell and Huntington and he said, no, and that's not how Dr. Alexander developed his model.

The last witness in this case, Your Honor, at trial was Ms. Colston, Stephanie Colston, who is an expert with extensive experience in evaluating treatment programs and abatement programs and she said -- she made the common sense point, but I think it's powerful, that you've got to know what you have before you allocate resources. How can we allocate $2.5 billion to a problem without knowing what the community is already doing?

Sort of a stunning thought, as she said, if you don't know whether the current resources are full or whether they're empty or they have a waiting list, how could you do -- how could you undertake the exercise? As she said, I don't see how you can evaluate need in a community without it.

And, in fact, as the Court has heard, there is a tremendous number of programs that are already operating in the City and the County. Sheriff Zerkle again colorfully said what we've turned into is a, quote, "recovery epicenter".

Dr. O'Connell described at some length the City of Solutions document and all of the programs that are already underway in the City and the County to address various opioid-related issues.

And Mayor Williams was asked about the City of Solutions document and the guide that was put in place to explain Huntington's successes in the fights against opioids and he said -- he was asked none of those programs is funded from the budget of the City and he answered and they never will be and never should be. Fine. But that really undermines the premise of this entire abatement model.

There's another flaw in Dr. Alexander's methodology. He deviated from his own methodology in a way that renders his report unreliable.

The Court may recall that Dr. Alexander had submitted the same kind of redress model in four different opioid cases. He developed what he calls an Apollo model, which is an extensive model with dozens of variables, many dozens of inputs of 25 or 40-page write-ups of how this model works and operates and he also described that he did extensive

calibration and testing to make sure that the model was accurate. He submitted that in Ohio in March, 2019.

He submitted a comparable model in the Washington litigation in January 20, 2021. Again, an Apollo model. Dozens of variables. Many dozens of inputs. Extensive testing and calibration.

Same thing in Rhode Island in June, 2021. His Apollo model submitted again; extensive, extensive testing, dozens of variables.

Well, what did he do here? He submitted a model based on the Jack Homer paper. He didn't use his own model. He used the Jack Homer paper. He had a one-sentence description of what he did, a one-sentence description as compared to this elaborate, extensive analysis of variables and inputs.

He did no calibration or testing because, as he said, it's not my model. I couldn't test it. Well, it just shows a shocking deviation from his own methodology. And there was no explanation provided as to why he deviated from his own methodology.

So, let's look a little bit more at the Homer paper. Dr. Alexander said it was important to consider funding as one is evaluating science. The funding has to be considered as one is interpreting the science.

He was unaware, he said, that the paper, the Homer

paper, was funded by two of the plaintiff law firms that are representing the plaintiffs in this case. Levin Papantonio represents the City of Huntington. Baron & Budd represents the Cabell County Commission. Those two law firms funded this Homer paper which bizarrely Dr. Alexander used rather than his own model.

Dr. Alexander also said that he'd never rely on someone he didn't know when he's evaluating one of these scientific papers. "I typically do consider the background and training of authors." So, I asked him, "Do you know who Jack Homer is?" "No, I do not." Pretty stunning. Pretty stunning in terms of how grossly he deviated from his own methodology. And these flaws of methodology undermine his entire opinion. They make it reliable -- unreliable and unsound.

But let's put aside the unreliability of Dr. Alexander's model.

Whoops. Sorry, Your Honor.

(Pause)

Let's put aside the unreliability of Dr. Alexander's model. There's an even more fundamental flaw. Dr. Alexander asserted that the success of his model was it would reduce opioid overdoses and overdose deaths by 50 percent over 15 years. That's -- that's his benchmark for putting in $2.5 billion in resources into a community of

90,000 people. It would reduce overdoses and overdose deaths by 50 percent over 15 years.

But that has already happened in -- in two years -- or three years between 2017 and 2019 and it did not cost $2.5 billion. The County and the City have already achieved the objective, the benchmark that Dr. Alexander articulated as his success for his own model. And the evidence reflects that between 2017 and 2019 there's been a reduction in opioid overdoses of 52 percent and overdose deaths of 46.7 percent.

This is further evidence that defeats any basis for awarding of funds to achieve an objective that the community has already achieved without these funds. There's no basis. When the City and the County are already achieving these objectives, there's no basis for the award being sought.

And, finally, and perhaps even most significantly, the plaintiffs have made no showing that the City or the County even need this additional funds to address the opioid crisis or to achieve their objectives. It seems to have been assumed, but there is no proof of that.

And, as we said, the City and the County are spending on opioid-related issues $136,000.00 today. And we see that the City is running a budget surplus of $17 million, which represents 25 percent of its budget. And the County is also running a surplus, although it's smaller.

Mayor Williams testified that he had no plans to allocate any of that surplus to opioid-related issues. There is no evidence of any additional funding needs to address the opioid crisis when the City and the County are not allocating any of their surplus to address the opioid crisis.

Furthermore, at the state level there are unused funds for opioids of roughly $80 million dollars, as Ms. Colston testified. Again, there is no evidence that the City and the County have made any effort to seek any of those funds for any purpose.

So, this is a complete absence of proof of any unmet needs for opioid-related issues that would support an award of funds to the City or the County, let alone a court-administered trust fund in the billions of dollars. There is no evidence that, in fact, the City and the County need more money in order to address the opioid crisis. They're doing a good job, but they have not made an evidentiary showing of more need for more funding.

So, in short, the plaintiffs have failed to present the Court with sufficient evidentiary bases to impose a remedy. Their obligation, as the plaintiffs, is to provide the Court sitting in equity with sufficient basis to exercise its equitable discretion in deciding on a remedy.

The failures of their methodology mean that the Court

is left without a sufficient evidentiary basis to act.

Just as in a damages case, a plaintiff seeking equitable relief must present evidence to support its claim for that relief. There's no such evidence here.

No evaluation of what's actually being done in the community. No evaluation of what more is needed. A flawed methodology based on a paper that was funded by the plaintiffs' law firms and with obviously flawed assumptions and estimates.

And virtually the entirety of the remedy being sought is to address the effects of opioid abuse; yet, the plaintiffs have waived damages in this case and are not entitled in their abatement case to recover for downstream harms from an alleged nuisance.

And virtually nothing in the proposed remedy is addressed to the distributors' conduct or to anything related to what the distributors have allegedly done to create a nuisance.

The plaintiffs cannot properly throw all of this into the Court's lap without sufficient evidence to guide its decision making and expect the Court to figure this all out. They've not done enough to come forward to the Court with a framework to permit the Court to impose the sort of remedy being sought.

So, there's simply no basis for the requested abatement

remedy in the record. It's unsupported by the evidence and it's demonstrably unreasonable at many different levels. We can tick off a lot of different levels where it's unreasonable.

But the Court need not reach these questions of remedy because the plaintiffs have not proven their case on the merits.

And so, to return to where I began, the evidence establishes clearly two points without contradiction. Doctor prescribing drove the increased volumes of prescription opioids and the plaintiffs' theory of harm is based on medicine cabinet diversion which resulted not only from prescribing decisions by doctors, but also from multiple criminal acts that plaintiffs' experts themselves recognized the distributors could not control and were not responsible for controlling.

Given this overwhelming evidence, the plaintiffs cannot establish proximate causation. *City of Charleston* and *Employer Teamsters* point the way. They establish the goalpost. They establish the framework. They decide the same issue that is before the Court now. They set the framework for decision.

And those cases were decided on pretrial motions. Here we have a full evidentiary record that defeats a showing of proximate causation, first, based on the intervening medical

judgments of doctors, a point that's culled out in both *City of Charleston* and *Employer Teamsters* as a very substantial factor defeating proximate causation. Second, we have the multiple intervening criminal actions of third parties giving rise to medicine cabinet diversion. *City of Charleston* speaks directly to that.

The evidence also defeats a claim of public nuisance. It cannot be a public nuisance to distribute a medicine that doctors are prescribing in good faith for the treatment of pain. Under the *Pope* standard the medical community has decided that the public interest, quote, "imperatively demands these medicines". Patients need them.

And under the Restatement formulation it cannot be an unreasonable interference with a public right to supply medicines that doctors are prescribing to treat patients. Distributors could not second-guess those decisions and it would be a perversion of the public nuisance law to suggest they should have counteracted and disregarded the medical judgments being made by doctors.

Public nuisance law would swallow the entire body of tort law if the harms from doctors' good faith prescribing of a medicine can be a public nuisance.

And public nuisance law would also override and swallow the regulatory judgments made by the FDA, the DEA, and the West Virginia Board of Medicine that encouraged and

facilitated the use of these medicines and that left the weighing of benefits and risks of these medicines to doctors and not distributors. Now, surely the plaintiffs got past pretrial motions on this point, but now we have a record that demonstrates the reasons that this cannot be a public nuisance.

So, I will conclude there, but I did want to conclude by expressing our very deep appreciation to the Court for its careful consideration of the evidence and for the many courtesies it has shown to all of us in this courtroom throughout this trial. It has been a pleasure to be before the Court and we are most grateful for the opportunity to present our case.

THE COURT: Thank you, sir.

MR. HESTER: Thank you, Your Honor.

THE COURT: Mr. Farrell, do you need some time to get set up?

MR. FARRELL: No, sir.

THE COURT: Are you ready to go?

MR. FARRELL: If they're finished, I'd like the opportunity to retort.

THE COURT: How much -- long do you think?

MR. FARRELL: I think less than 30 minutes, Judge.

THE COURT: Okay. Then we'll press on, if you're ready.

MR. FARRELL: Over the past several hours it's been difficult to sit by and listen to some of my colleagues. On behalf of the City of Huntington and the Cabell County Commission, we take great offense at some of the misrepresentations, we believe, of the record.

This is Day 40. This is Day 40, appropriately so, and I'm not going to go through every single one. This isn't a high school debate where we're trying to keep a scorecard of points. But there are a couple of individual points that I do want to bring this Court's attention to.

First, we find it remarkable that throughout the three closing arguments not a mention was made of the highest court in the land who has commented upon the duty owed by the distributors in *Masters Pharmaceutical*. Not a word was mentioned of the duty to maintain effective control.

The next point. Supply driving demand. It's not a concept to be dismissed easily when we're talking about opium. We're talking about a controlled substance defined by 21 U. S. C. 812, Subparagraph (2), Subparagraph (b).

We're talking about opium. To pretend that the supply of opium doesn't create addiction and demand totally ignores the entire premise of why we've regulated this drug as a controlled two substance. It is a metastasized cancer in our body politic and will continue to grow.

Opium has been around since the Byzantine era. It has

toppled governments because it, by its very nature, is addictive. You can't get opioid addicts without a supply of opium.

When you look at the *Direct Sales* case, Judge Faber, when you look at the case and you read the volume was the premise in *Direct Sales* and the United States Supreme Court said that the volume of morphine sulfate sold by the wholesaler to the dispensing physician, and I'm quoting at 319 U. S. at 712. 319 United States Reports at 712. "The primary effect is to create black markets for dope and increase illegal demand and consumption." In this instance, the supply in part was fueling demand.

Next point.

THE COURT: What were the facts in that case?

MR. FARRELL: So, in that case, you had a wholesale distributor that was selling morphine sulfate tablets by mail order and, back then, to regulate the industry you had to have, under the Harrison Narcotic Act, you had to have a stamp book.

So, down in South Carolina, in a town of 2,000 people, a Dr. Tate was ordering some 6,000 tablets a month. And there was an indictment of three individuals that had been using these morphine sulfate tablets.

There was an indictment of the dispensing Doctor, Dr. Tate, and there was an indictment of the wholesaler. And

they got convicted. The wholesaler was convicted of criminal conspiracy and appealed it all the way to the United States Supreme Court.

And when you look at -- and I had it written down. When you look at -- well, I have it here in my hand, Judge. Page 713.

And, actually, if I may I approach, I've highlighted it.

At Page 713 of the case what you'll see is the defense -- what you're reading is the standard of care defense that you just heard for a day and a half. In that case, the wholesaler said wait a minute. We were providing morphine sulfate to a doctor that had prescribed it and he had a stamp book. And the United States Supreme Court says that doesn't give you immunity, that just because a physician prescribed it doesn't mean that what you weren't doing was facilitating criminal diversion.

To be clear, Judge, the exact offense that's in the paragraph I highlighted for you is what we just heard all day today. And it was not only insufficient defense in the United States Supreme Court case but, respectfully, Judge, it was an insufficient defense in closing argument up on the sixth floor on May 28th of this year. While this case was pending they convicted a doctor for prescribing medicines.

The standard of care defense didn't work in this case

in 1943. It didn't work upstairs. And it shouldn't work here.

Now, the next point.

THE COURT: According to the scope note in the case, it says that the seller not only knew the physician was selling the drug illegally, but it intended to cooperate with him. So, that makes that case a little bit different than this one, doesn't it?

MR. FARRELL: Well, no, Judge, because when you read the body of the case what the United States Supreme Court said is that there was no actual agreement. There was no overt act of what you just said. The United States Supreme Court says that when you sell that much it infers that you are acquiescing.

So, when you read the entire length of that opinion what it suggests is that when you act over such a period of time with such volume, you are deemed to act not only in mind, but in hand, to further and facilitate the diversion of controlled substances.

THE COURT: That was in 1943.

MR. FARRELL: Yes, sir.

THE COURT: We didn't have the regulatory framework that you have that applies here, correct?

MR. FARRELL: That is correct. That's why you'll recall from Dr. Courtright, Dr. Courtright said is that, in

1970, we created one organic body of law and codified the closed system. This Harrison Narcotic Act was just the infant of the more complex regulatory system we have today.

But the point of the matter is, is that there has been a recognition in the United States for a significant period of time that if we don't control narcotics then they will get out into the black market.

THE COURT: That's what the DEA is all about, isn't it?

MR. FARRELL: Yes, sir, it is, and that's why the DEA has been attempting to implement the system designed by Congress and the one part of the system the DEA has consistently been arguing with the defendants about is their role in the system.

So, the facts of this case, we may very well agree on a lot of the facts. We may very well agree that doctors were writing too many prescriptions. They should agree that there are doctors that went to prison.

We all agree that if you -- if you make, sell, distribute prescription opioids you have to be in the closed system. No one disputes the number 81 million.

The real dispute in this case is whether or not the defendants, the distributors, have a duty to control supply. Respectfully, Judge, if they have no duty to control supply, they shouldn't even need a registration. They should just

need delivery trucks.

They have a duty, they have a duty in supply, then there is an abrogation of that in Huntington-Cabell County, West Virginia. And the reason I say that is because the volume of pills that were sold is clearly unusual. Clearly deviating from the normal pattern.

So, I respect the fact that since 2005 Cardinal Health, McKesson and AmerisourceBergen have steadfastly denied that it is their responsibility to control the supply of prescription opioids. I respect the fact that that's their position.

The DEA has on this record with Mr. Prevoznik testified that they were in violation of their regulatory obligations. The DEA told them so. The DEA warned them. Provided notice. Sanctioned them. Sanctioned Cardinal Health twice, the second time resulting in an acknowledgment of wrongdoing. Sanctioned McKesson twice, the second time with McKesson acknowledging wrongdoing. And that, nonetheless, today in this courtroom the three companies are continuing to say the same thing, it's not their duty.

What that tells me, Your Honor, is that if this happens again, they would do it again. If, in fact, it's true that the only thing that they need is an order form from a registered pharmacist and that's all they need, that's the defense that was -- the exact defense rejected in the *Direct*

Sales case.

What's the purpose of a closed system if we're not going to try to regulate and keep the pills for legitimate medical needs?

I want to take a brief minute and make a comment about James Rafalski because he's a good man and I think his credibility has been disparaged by the defendants today.

What Mr. Rafalski's testimony is about is that assuming -- just assume for the fact that there is a duty for the defendants to monitor unusual patterns. Let's just assume they had that duty. The question then is what is unusual and, once you detect an unusual pattern, what do you do about it?

So, one of the reasons that I gave you the big, big wieldy charts is so that you could see in some absurd conclusion with hydrocodone pills that, at some point in time, there were, in month one, 180,000 hydrocodone pills sold to a pharmacy in Logan County.

Now, let's just take that for a minute. If, in one month, you sell 180,000 hydrocodone pills to a pharmacy in Logan, what is your immediate response? My immediate response is that's -- that's too many pills.

When I look at it and I see that the national average is 3,000, the state average is 3,700, if you're selling 180,000 to 1 pill (verbatim), there's a mistake. Something

should happen.

What Mr. Rafalski's testimony is and what his common sense is that if you get an order for 180,000 pills, somebody should probably stop and check and make sure that this isn't a mistake because it seems like it's a clerical mistake.

You shouldn't ship 180,000 pills to a pharmacy in Logan. And if you have a system that has some type of safety valve, 180,000 should be enough to trigger the safety valve. And if the safety valve gets triggered what we should not see is the next month another 170,000 pills.

THE COURT: Well, what does a pharmacy in Logan have to do -- a situation in Logan County have to do with Cabell County and the City of Huntington?

MR. FARRELL: Okay. I -- I'm using the pharmacy in Logan as an absurd spectrum to demonstrate why Mr. Rafalski is being criticized here. Mr. Rafalski is trying to demonstrate that once a system --

THE COURT: Well, you can't put an expert on the stand in a case that's this important and expect him not to be attacked, Mr. Farrell.

MR. FARRELL: I -- I understand, Judge, but you also, I would hope, allow me for the opportunity to defend him.

THE COURT: Well, you're doing a pretty good job.

Go ahead.

MR. FARRELL: So, by applying these same metrics to Cabell County what we're attempting to demonstrate is that something unusual happened.

Now, the final thing before I move into what ultimately I want to discuss is about the abatement plan and I'm going to -- I'm going to quote my co-counsel, Ms. Ann Kearse. This is the line that she gave me that I think perfectly captures what my heart is on this.

We shouldn't let the perfect be the enemy of the good. And I think that sums up what this abatement plan is. You can poke holes in it. You can criticize it.

But what you haven't seen, Judge, is an alternative proposed by the defendants. If you find them liable, they have not put in an alternative plan. All they have attempted to do is convince you to award less money.

So, what I thought about before listening to the comments, what I wanted to say to you, Judge Faber, before we ended --

Will you bring up the slide?

So, I like to fish and I understand that you may have, too.

THE COURT: So do I, Mr. Farrell.

MR. FARRELL: And so, this is not the Cranberry River, but it very well could be if those were rhododendron

bushes that were hanging over.

And I lived with my wife Jackie up in Morgantown for a period of time. And what we used to do is we used to pop over into Maryland and then straight down to a little town called Barnum, West Virginia, which is on the south branch of the south fork of the Potomac right at the tail waters of the Jennings Randolph dam.

THE COURT: I know it well, Mr. Farrell.

MR. FARRELL: So, if we go to the next slide, please.

What we would do, and this is how big of a nerd I was about it, I would look at the output of the Jennings Randolph dam and watch for subtle changes in the output. And then I would watch to see with the rain and the output how it had subtle changes in the gauge of the height and what it did to water temperature because we were monitoring these outputs because little subtle differences can make a big thing.

That, to me, is what I hear when I hear the defendants talk about their monitoring and the subtle changes in the practice of medicine. But this isn't what happened in Huntington-Cabell County, West Virginia. What happened was something different.

That's what happened here. The Upper Gauley. I've been to the Upper Gauley. I've stood on those rocks. I've

watched that water come out.

Judge, this isn't a subtle change in the behavior of practices that happened as the sole cause. This was a blowout. If we were to take the measurements at Barnum, those fancy Corps of Engineers measurements, and we were to measure what happened in Huntington-Cabell County, it wouldn't look like those subtle changes in water level. It would look like this. That's what -- that's what the water levels would look like.

So, go to the next one, please.

So, here -- here's kind of the metaphor that I want to draw about what the defendants are saying. The defendants are the dam and they're standing up on top of the bridge there. They're standing up above the water and they're looking down. And the volume of water that comes out is under their control.

Now, this isn't an issue of the safety valve failed. This volume of water here at the -- at the bottom, at the bottom of Summersville Lake here, somebody turned it on. It's not an accident. They had to turn it open.

That's what's the difference here, Judge. This isn't that the distributors were just passengers on this event. They -- they weren't, you know, standing by watching it.

What they are, they're active participants charged by the United States Code and the Code of Federal Regulations

to be responsible for the control valve. They're the ones that are supposed to see not just the subtle changes in the water levels, they're supposed to prevent the blowouts.

And that's what we had in this case, was we had a blowout. We had 81 million pills that came flooding into our community and it wasn't by accident, Judge. Somebody delivered those pills here and it was the distributors.

Their argument that they were all prescriptions written by doctors is insufficient to immunize them or a safe harbor for their regulatory responsibilities. If they don't want to be responsible for controlling the volume of prescription opioids, they should get out of the business. The reason they don't want to get out of the business is they don't want to lose the bigger accounts.

This is a component of their job, to watch for, to monitor -- design, monitor, and to block orders that are suspicious. And if the number of pills that came into Huntington-Cabell County, West Virginia isn't suspicious, I don't know what is.

The causation argument is best stated by Ms. Colston, the very last witness in this case, and what she acknowledged is we don't have to show that the dam operator is the cause of the -- of the flood. They only have to be a substantial cause.

And if the defendants owe a duty, and if they breach

that duty, they are certainly a proximate cause. And to stand by and to say that it has nothing to do with them when the community downstream from this got wiped out defies the very nature of the closed system.

So, in closing --

You can take that down.

As a historian, you're going to know that there's a very old story, one I'm fond of, and that old story has a man who is walking down a road and he comes upon ten lepers. And I've heard this story told, re-told, many times, but I wanted to share with you a version that I overheard which holds some weight and significance in my mind.

You see, we call the story -- we originally call the story *The Ten Lepers*, but it was originally written in Greek, and then translated to Latin, and then I heard it in English. And the Greek word is lepra (phonetic) and it's not that this man walking on the street came upon ten lepers. The Greek word is that he came upon ten men with leprosy.

You see, even in that old book, it recognized that these were ten human souls that suffered from leprosy and that leprosy didn't define them as lepers, it's what they were suffering from. And this distinction makes a lot of difference in the mission that we have because we have human souls that are suffering from addiction.

So, you see, I have not lost faith that we can cleanse our community, Judge, but faith alone may be insufficient. What we need to do is a lot of work. And after four years, my work is now done, and I -- I truly believe in my heart that I have done all that I can and now we entrust this work to your capable hands. Magic or tragic, there will be a reckoning.

Thank you for your time and patience.

THE COURT: Thank you, Mr. Farrell.

I assume you want to submit revised proposed findings and conclusions; is that right?

MR. MAJESTRO: Yes, Your Honor.

MS. MAINIGI: Yes, Your Honor.

MR. HESTER: Yes, Your Honor. That's the plan.

THE COURT: How much time do you need to do that?

Get my instructions here.

(Pause)

THE COURT: My advisor has offered the choice between two and three weeks from today.

MR. MAJESTRO: We would prefer three. The other -- the other question I have for my colleagues on the other side of the aisle is whether they intend to file replies on the Rule 50(c) motions?

MR. HESTER: Yes, we do.

MR. MAJESTRO: We would like to see those before

we file our final -- final proposed order.

MR. HESTER: Your Honor, we needed a little time to work both on the Rule 52 replies, as well as -- as well as the findings. Could we have two weeks from today to submit the replies and three weeks from today to submit the findings?

THE COURT: Is that all right with you, Mr. Majestro?

MR. MAJESTRO: That works for us, yes. Yes, sir.

THE COURT: All right. That's what we'll do.

All right. Is there anything else before we adjourn?

I want to thank the lawyers for the character and competence and the quality of your work. It's made what otherwise would have been a very unpleasant several weeks much less so.

(Laughter)

THE COURT: And I want to thank all of you for your hard work and the way you've treated the Court. I appreciate it very much.

And I'll wait to see your submissions.

SIMULTANEOUS SPEAKERS: Thank you, Your Honor.

(Trial adjourned at 2:55 p.m.)

CERTIFICATION:

I, Ayme A. Cochran, Official Court

Reporter, and I, Lisa A. Cook, Official Court Reporter, certify that the foregoing is a correct transcript from the record of proceedings in the matter of The City of Huntington, et al., Plaintiffs vs. AmerisourceBergen Drug Corporation, et al., Defendants, Civil Action No. 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as reported on July 28, 2021.

S\Ayme A. Cochran
Reporter

s\Lisa A. Cook
Reporter

July 28, 2021

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